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Biomedical Applications Team

Innovations in health care using aerospace technologies

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UNIVERSITY OF WISCONSIN-MADISON

Advisory Center for Medical Technology and Systems

FINAL REPORT

July 1, 1976 to December 31, 1978

Contract NAS5-23500

January 15, 1979

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Director, UW-BATeam

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SUMMARY

Periods of Performance

A contract from the NASA Technology Utilization Office creating a Biomedical Applications Team at the University of Wisconsin-Madison was first awarded in mid-1974. Since that time, the UW-BAT has operated continuously under successive contracts.

The present report covers the time span of July 1, 1976 through December 31, 1978, a 30-month interval broken into two distinct periods. The first 18 months, from July 1, 1976 through December 31, 1977 was devoted to full-scale normal operations of a BAT as described in Section II of this report. The last 12 months, covering the period January 1, 1978 through December 31, 1978, was devoted solely to a project specifically authorized under a contract extension. Period I and Period II will be used herein to refer to these separate periods.

Work accomplished under the first 18-month period will be discussed in Sections III and IV of this report. Work carried out during the 12-month extension period will be covered in Section V.

Period I Summary

As a consequence of carrying out normal BAT operations during this period, a total of 21 new problem statements were prepared for distribution to NASA field centers. A list of these, beginning with UW-30, can be found in Appendix A. Of the total under consideration during the period, 16

problem statements were dropped from further consideration. These are identified in Section IV under "Inactivated Problem Statements" and brief details are given concerning the inactivation in each case. We were left with 21 active problem statements to carry over into the new year. Section III of the report contains complete statements of each of the remaining active problems.

Aside from problem statement activity, the Team worked to help commercialize several devices produced under separate RTOP funding. Two of these, the JPL Burn Analysis System and the GSFC Lixiscope were demonstrated to potential manufacturers at conferences arranged by members of the UW-BAT. A third, the JPL Proctosigmoidoscope was reviewed by a Team member in preparation for possible further development of the device but plans to continue work on the device were dropped by the center.

A number of special reports were produced in response to requests from Headquarters and field centers, and these are identified in an annotated listing at the end of Section IV.

Period II Summary

The contract period was extended by 12 months, specifically to carry out a project on the needs of the elderly. During this 12-month period (which fully overlapped a sequentially awarded contract to support normal BAT operations at the University of Wisconsin), a special effort was put forth to analyze needs of the elderly in terms of opportunities for solution available through the NASA TU program.

The project was organized into seven discrete tasks. These are shown in Section V of this report, followed by a running synopsis of work accomplished under the contract extension.

SECTION II

THE NASA BIOMEDICAL APPLICATIONS TEAM PROGRAM

THE NASA BIOMEDICAL APPLICATIONS TEAM PROGRAM

INTRODUCTION

The Technology Utilization Program

Biomedical Applications Teams are an important element of the overall NASA Technology Utilization Office. The Technology Utilization Office was established in 1962 for the following purposes:

1. To increase the return on the national investment in aeronautical and space programs by helping to bring about additional uses of the knowledge gained in these programs.
2. To shorten the time from development of new knowledge to its dissemination and effective utilization.
3. To aid the movement of new knowledge across organizational, disciplinary, and regional boundaries.
4. To help develop better methods for communicating and applying government-generated knowledge to private industry.

The Office has organized its activities on a nationwide basis (transfer network) to promote effective utilization of the vast amounts of new technology and other technical information generated by aerospace research and development programs.

PROGRAM (GENERAL)

The Biomedical Applications Teams

Biomedical Applications Teams (BATeams) were established by NASA in 1966 for the specific purpose of transferring aerospace technology to the solution of biomedical problems. Basically, each BATeam acts as an interface (broker)

between the medical profession, rehabilitation centers, mission agencies, manufacturer, and NASA scientists and engineers. Team members met with investigators in the medical and biological sciences, physicians, and medical specialists, to define significant technological problems. This methodology demands that specific medical needs are identified and defined through direct contact with potential users of aerospace technology. Only those problems are considered which meet the following criteria:

1. No ready solution is available through commercial medical instrument manufacturers. That is to say that the new or improved products are probably made possible only through the use of NASA technology.
2. The problem can be defined in terms such that an aerospace related technology could be applicable to a solution.
3. Solution of the problem would make a significant contribution to medical research or clinical medical practice. The emphasis, therefore, is on identifying and commercializing those applications of NASA technology that are significant commercialization opportunities or provide major medical breakthrough.

There are three Biomedical Applications Teams established at the following institutions:

1. Stanford University School of Medicine
   Cardiology Division
   Biomedical Technology Transfer
   701 Welch Road - Suite 3303
   Palo Alto, California 94304

2. Research Triangle Institute
   P.O. Box 12194
   Research Triangle Park, North Carolina 27709

3. Advisory Center for Medical Technology and Systems
   University of Wisconsin
   1500 Johnson Drive
   Madison, Wisconsin 53706

Technology Transfer Process

The term "technology" itself is very broad, including both hardware and software, as well as the engineering expertise that has been a part of aerospace projects. There are many different ways in which technology developed through the space program can be applied or transferred to solving biomedical problems. No single approach to transferring technology to medicine is applicable to all medical problems. The approach is adapted to the particular problem and institution involved. However, the general procedure followed by the Biomedical Applications Teams consists of four basic steps:

1. Identification of Commercialization Opportunities
2. Screening of Commercialization Opportunities
3. Development of Commercialization Strategy
4. Implementation of Commercialization Strategy

These steps are described in the following paragraphs.

PROGRAM (SPECIFIC)

Identification of Commercialization Opportunities - In order to identify commercialization opportunities, the Team serves as an active interface between medical investigators and the body of scientific and technical knowledge that has resulted from this nation's aerospace research program. The Team attempts to carefully define the technological needs facing the medical community and to identify relevant aerospace technology to solve those needs. The needs are those encountered in clinical and rehabilitation medicine and medical research programs in major clinics and medical schools and in the National Institutes of Health. The Team actively engages in the identification of these needs through direct contact with the clinical

rehabilitation and medical research staffs. The objective is to define precisely and accurately the characteristics of the technology required to solve the needs. In many cases, following the characterization of the required technology, it is obvious that the need should not be considered by the Team. The "should not" reasons could include the following: (1) the need can be solved using commercially available equipment; (2) the need cannot be solved, so that an entirely different approach is indicated; (3) the real problem is medical and not technical in nature; (4) the possible solutions would have little probability of being commercialized; and (5) the requirements cannot be specified because insufficient information exists.

After the problem is defined, a BATeam member confers with the problem originator. Clarification of technological aspects of the problem leads to the formulation of a "Problem Statement." Besides defining the problem in greater detail, the Problem Statement answers the following questions:

1. What medical specialty is involved?
2. How has this problem been solved in the past?
3. What presently available commercial equipment is applicable?
4. What broad medical impact will solution of the problem have?
5. Can the technological solution offered by NASA be readily made commercially available?

Aerospace technology that may be relevant to the solution of a need is identified by three approaches. First, a manual (or computer) search is made of the aerospace information bank. These searches are made at one of NASA's six Industrial Applications Centers (IAC). On-line computer searchers utilize the NASA Scientific and Technical Information Facility in BWI Airport, Maryland. The information that can be accessed through the information bank consists of more than one million documents, articles, and translations that

have been abstracted in the Scientific and Technical Aerospace Reports (STAR). The International Aerospace Abstracts (IAA), Computer Program Abstracts, Tech Briefs, and in many other publications. Second, the Team contacts individuals at the NASA Field Centers who are likely to have a good overview of all work being done, which is related to the requirements of a specific medical need. Third, problem statements are circulated in a highly selective manner with the distribution being determined by the Team, Technology Utilization Officers (TUO) at the NASA Field Centers, and other individuals at the Field Centers.

All potentially relevant technology that is identified by the search procedures is evaluated by the Team to determine whether a potential solution to a specific need has been found. Those items of technology that represent potential solutions to needs are presented to problem originators along with available supporting data and information. Any required re-engineering (and the details of implementing the potential solutions) are discussed with the problem originator.

The problem originator and the Team must then work together to evaluate potential solutions. Their decision to implement a proposed solution will depend upon a number of factors: (1) their assessment of the technical validity of the proposed potential solution; (2) the medical applicability of the proposed solution; (3) consideration of the cost and time necessary to complete the implementation; and (4) appreciation of factors which would contribute to later development of a commercially attractive device. They should evaluate the appropriateness of the proposed solutions and select one solution for further action. Then, the team prepares a commercialization package which describes the solution, the medical need, the patent status, and various pertinent aspects of the potential market. This package is used to aid in the identification of a manufacturer.

Those solutions that have been selected by the above procedures are subjected to the second step--screening of commercialization opportunities.

Screening of Commercialization Opportunities - Effective screening of commercialization opportunities is at least as important to the success of the Biomedical Applications Team Program as any of the operational steps. For it is through this screening process that the Team identifies those commercialization opportunities that have a high probability of being commercialized. In addition, much of the data used in the development of commercialization strategy is accumulated during this process. Currently, the following criteria are being utilized to screen commercialization opportunities:

(a) The solution uses NASA technology or expertise.

(b) The solution provides an innovative improvement in treatment or diagnosis, or it results in a reduction in cost of health care.

(c) The solution will have a significant impact on the medical field, and the character of that impact will be positive.

(d) The market size is adequate for the necessary capital risks, and the solution can be manufactured at a cost which will permit penetration of this market.

(e) A latent demand exists for the solution, or a demand can be created using pertinent marketing techniques.

(f) The potential manufacturers are identified who are willing to join a NASA-Industrial-Medical Team to commercialize the solution and who will agree to sharing the costs of this development effort.

(g) The existing distribution patterns and organizations that will move the product from the manufacturer to the potential user, if not an integral part of the manufacturer's organization, are identified.

(h) The funding for the necessary development, engineering evaluation, and marketing necessary to commercialize this solution have been tentatively identified, with all or most of the funds coming from sources other than NASA.

Commercialization opportunities that do not satisfy these criteria are rejected or placed into a category entitled "Institutional" (more than 50% co-funded by a mission agency) or "Demonstration" (more than 60% co-funded by a mission agency). In all cases that are not coupled with a manufacturer, NASA conducts a market study to learn more about the potential for widespread use. Those that do are classified as having a high probability of being commercialized and are documented in a commercialization opportunity report. The Team now initiates the third step--development of commercialization strategy.

Development of Commercialization Strategy - Studies have clearly shown that the manufacturer must be involved early in the product development procedure. Therefore, the Team immediately undertakes the identification of a suitable manufacturer. Copies of the commercialization package, which describes the commercialization opportunity, are forwarded to suitable manufacturers. An officer for each of these manufacturers is personally interviewed. thus, favoritism is avoided. Once the manufacturer is identified, the NASA-Industrial-Medical Team is formed. The role of each member is defined and any agreements which are found necessary, such as licensing arrangements, are negotiated. This newly formed NASA-Industrial-Medical Team, with the Biomedical Applications Team now acting as a consultant and coordinator (broker), must create the product development and marketing plans. The costs of carrying out these plans are estimated, and it is agreed how much of this cost each member will underwrite. If costs cannot be covered by the NASA-Industrial-Medical Team, sources for the necessary additional funds

must be identified. Possible sources are such organizations as the National Institutes of Health, the Rehabilitation Services Administration, the Veterans Administration, and others.

The distribution of the finished product can pose a serious problem. It must be carefully considered in the marketing plan, since many manufacturers do not have their own product distribution and product maintenance systems. These needs must be met. They may require the addition of a fourth member to the NASA-Industrial-Medical Team. Unfortunately, the cost of such a distribution system can make it economically impossible to market the NASA device. Therefore, it is best to learn this before the expenditure of much time, money, and effort.

Two other factors which must be considered are: (1) the special medical testing required by such organizations as the Food and Drug Administration; and (2) the effort to develop a new market. Both of these needs are usually adequately provided for if care has been exercised in the selection of the manufacturer. If properly qualified, the manufacturer will have extensive experience in both of these areas. If either factor is not considered in the selection of the manufacturer, the commercialization effort will almost certainly fail.

Funding sources must be identified. Ideally, NASA funding will not be required. Rather, all or most of the funding will normally be provided by the government agency that has the primary responsibility for the particular area of medical need. As an example, when the medical need involves some cancer treatment technique, the government agency to provide most of the funding would be the National Cancer Institute. If NASA funding is needed and can be justified, the Team will work closely with the involved NASA Field Center to prepare the necessary Research and Technology Objectives and Plans (RTOP) for submission to NASA Headquarters. However, before submission of the

RTOP, the commercialization strategy has been completed and the commercialization opportunity has been classified as a potential commercialization: (1) the NASA-Industrial-Medical Team has been formed; (2) the development and marketing plans have been completed; (3) the sources of co-funding have been identified; and (4) the potential commercialization report has been prepared and distributed. Descriptions of this strategy become an integral part of the RTOP.

The formal approval of the RTOP by NASA Headquarters or, in the case where an RTOP is not required, the approval of the commercialization strategy by the NASA-Industrial-Medical Team will initiate the final step in the Team methodology-implementation of commercialization strategy.

Implementation of Commercialization Strategy - In this final step, the role of the Team is one of monitoring, coordinating, and reporting. However, this Team activity is vital to the success of the commercialization effort. By carefully monitoring and coordinating the activities of individual members of the NASA-Industrial-Medical Team, minor problems can be prevented from becoming major obstacles. In addition, the project overview held by the Team, plus knowledge of the technology transfer process, gives the Team considerable insight as to the possible sources of difficulties. Thus, the Team can help guide the project around these problem areas.

Reports and documentation are an integral part of the Team methodology; they are involved at most steps in the transfer of technology. The step involving the implementation of commercialization strategy is no exception. Periodic status reports must be issued to keep all interested parties informed. Upon completion of a commercialization, the Team must prepare a commercialization report. The resulting reports and documentation facilitate a later analysis of the entire technology application process.

TERMS OFTEN USED

In the Biomedical Applications Team Program, a number of terms have evolved that describe the elements and processes in this program. Because of their number and unfamiliarity to many readers, these terms are listed and defined for reference.

Biomedical Applications Team (Team) - The Team is a multidisciplinary group of engineers and scientists engaged in the activities of identifying the technological needs in medicine and rehabilitation and the appropriate aerospace technology to solve those needs with the specific objective of effecting the commercialization of the resulting solutions. The methodology used by the Team involves: (1) Identifying Commercialization Opportunities - select and define significant medical technological needs and the appropriate solutions that use NASA-developed technology; (2) Screening Commercialization Opportunities - identify those commercialization opportunities that have a high probability of being commercialized; (3) Developing Commercialization Strategy - form a NASA-Industrial-Medical Team, and create the necessary development and marketing plans, including identifying the necessary funding; and (4) Implementing the Commercialization Strategy - coordinate and monitor the NASA-Industrial-Medical Team implementation of the commercialization strategy.

Commercialization - The application of NASA technology may result in a marketable product. A commercialization occurs when this product, or a variation that also contains the NASA-developed technology, is announced and/or made commercially available to the public.

Commercialization Opportunity - The efforts of the Team have led to the identification of NASA technology which solves a significant medical need. This technological solution is carefully screened. A commercialization

opportunity is a solution that has been identified by the screening process to have a high probability of being commercialized.

Computer Information Search - A computerized information search is a search of the aerospace information bank established by NASA and made available through six Industrial Applications Centers (IAC) in the United States. This information bank consists of more than one million documents that have been indexed and abstracted in the Scientific and Technical Aerospace Reports (STAR) and the International Aerospace Abstracts (IAA).

Impact - An impact is reported when information is given to a problem originator with the result that he changes his activities in a way that enhances his progress toward a medical objective. Thus, an impact is analogous to a technology application except that some requirements for a technology application are not satisfied.

Need - A need is a specific and definable technological requirement that cannot be satisfied by commercially available equipment or by application of information that is available to the problem originator through routinely used problem-solving channels (e.g., hire a bioengineer).

Participating Institution - A medically oriented educational institution, hospital, medical center, or government agency having as one of its organizational objectives the improvement of medical health care is listed as a participating institution. . . if an interactive relationship with a Team is established.

Potential Commercialization - When the efforts of the Team have led to the organization of a NASA-Industrial-Medical Team to work on a commercialization opportunity, and to the development and implementation of the commercialization strategy, including the tentative identification of funding, the work is said to be at the stage of a potential commercialization.

Potential Technology Application - The search for NASA technology by the Biomedical Applications Team leads to the identification of relevant technology that offers strong potential for solving the particular needs. A potential technology application occurs when the Team and the problem originator agree on the applicability of the specific NASA technology to the particular need and when a reasonable plan for achieving implementation exists.

Problem Originator or Researcher - A problem originator is an individual actively involved in an effort to reach a specific objective in biology or medicine and faced with a specific technological need that is impeding progress toward achieving that objective.

Problem Statement - A problem statement is a concise, written statement of a need used for communicating: (1) sufficient details to allow a computer search to be performed by the information search specialists; and (2) sufficient information to enable NASA engineers and scientists to consider possible solutions to the need. This document should not be confused with a preliminary problem statement which is a one-page brief description of the need. This document is designed to initiate the solution search.

RTOP (Research and Technology Objectives and Plans) - The Biomedical Applications Team has helped organize a NASA-Industrial-Medical Team to pursue the commercialization of a commercialization opportunity. Development, funding, and marketing plans have been prepared. An RTOP is a comprehensive proposal made by a NASA Center to NASA Headquarters for funding to support this commercialization effort.

Technology Application - The key factor that permits a potential technology application to become a technology application is implementation. A technology application occurs when aerospace technology is implemented

to solve a need different from the one for which the technology was originally developed.

Widespread Use of Technology - The application of NASA technology solves a particular medical need. Widespread use of technology occurs when this solution, or a variation that also contains the NASA-developed technology, causes a service or a device to become available to a wide segment of the public.

THE UW-BAT

History

The University of Wisconsin-Madison was awarded its first contract to operate a NASA Biomedical Applications Team in 1974. This final report is the third such report to be filed by the UW-BAT, which is now beginning its fourth full year of operation.

The original proposal to NASA stressed, as one important component, the importance of transfering technology to the primary level of the health care delivery system. Primary health care is delivered during the first or most basic form of encounter between an individual and the health care system. It is also the most common form, encompassing such activities as routine office visits, preventive medicine, and emergency medical care. The health care providers involved are generally found in general or family practice, pediatrics, and internal medicine. Included, as well, are dentists, paramedics, and physician extenders of various types--in short, those who help patients when they first appear with medical needs.

The UW-BAT concept of operation has been specifically oriented to technological needs in primary health care delivery. As part of this emphasis, the Team has been particularly active in areas of emergency care

systems, such as telecommunications. Since the patient plays a greater role at the primary level, much of our work has been directed at his needs, in addition to those faced by providers.

Organization

The members of the UW-BAT are drawn from the professional staff of the Instrumentation Systems Center at the UW-Madison. This Center is a division of the Engineering Experiment Station of the College of Engineering at the University. Currently, five biomedical engineers work on the program. Three of these split their time between BAT work and other projects being carried out within an ISC organization called the Advisory Center for Medical Technology and Systems. The Team also has ties with the Department of Family Medicine and Practice, through the department chairman, who acted as co-principal investigator for the contract.

Operations

The Team acts to carry out the NASA Biomedical Applications Team Program, discussed above, through extensive personal contact and frequent travel. Medical problems involving technological needs are identified by visiting medical facilities, attending professional conferences, and by referral from other NASA/TU units. These are processed by individual Team members, who carry out the searching, matching, evaluating, and organizing activities as required. Team members are also frequently asked to consult with NASA personnel on matters pertaining to the overall mission of the NASA Biomedical Applications Program. The Team, itself, also works with paid consultants to help carry out its own program.

ACRONYMS

Following is a list of acronyms used frequently in this report. The numbers in parentheses are the pages of the report on which a further explanation for each can be found.

ARC	Ames Research Center
BAT	Biomedical Applications Team (16)
COSMIC	Computer Software Management & Information Center
DFRC	Dryden Flight Research Center
GSFC	Goddard Space Flight Center
IAC	Industrial Applications Center (17)
JPL	Jet Propulsion Lab, California Institute of Technology
JSC	Johnson Space Center
KSC	Kennedy Space Center
LaRC	Langley Research Center
LeRC	Lewis Research Center
MAT	Manufacturing Processes Applications Team
MSFC	Marshall Space Flight Center
RTOP	Research and Technology Objectives and Plans (18)
TAT	Technology Applications Team
TU	Technology Utilization (NASA program and Office) (7)
UW	University of Wisconsin-Madison (19)

SECTION III

ACTIVE PROBLEM STATEMENTS

PROBLEM STATEMENTS

Problem UW-6 - Unobtrusive Bio-feedback Device for Treatment of Petit Mal Epilepsy

The Need: An unobtrusive device to continuously monitor the electro-encephalogram (EEG) of children in their normal environment, process the signal and provide an audio feedback for a particular waveform. Particular needs are for (1) an electrode system for long-term, continuous application and which will produce usable EEG signals, and (2) signal processing circuitry.

Background: Epilepsy is a major health problem affecting an estimated 2 million individuals. Petit mal is a type of epilepsy which typically affects children between the ages of 2 and 16, and is characterized by momentary or brief loss of consciousness. There is no apparent perception or recollection of the blackout by the individual. The duration and frequency of seizures vary widely and may last from 20 seconds to several minutes, and occur as frequently as every five minutes. Petit mal is distinguished from grand mal, the classic convulsive of epilepsy, in that it generally afflicts children and usually either dissipates or becomes grand mal near the end of adolescence. While not as traumatic as other forms of epilepsy, petit mal seizures can result in significant learning problems for children affected, as well as social stigmatization and many difficulties. Currently, anti-convulsive drugs are the most

effective way of controlling petit mal epilepsy. The prototypic drugs for the therapy of petit mal are trimethadione and ethosuximide. Both drugs have side effects and require close medical supervision, especially in the first year. The most common side effects from ethosuximide are gastrointestinal complaints of nausea, vomiting, loss of appetite; nervous system effects such as drowsiness, dizziness, headaches, lethargy; etc. All of the drugs used in petit mal therapy can produce a variety of undesirable and potentially dangerous side effects. Thus alternatives to drug therapy, such as the suppression device, would offer potential advantages to both the doctor and the patient in the treatment of petit mal.

The BATeam had been previously involved in the refinement of a miniature wearable device for the suppression of acoustiomotor epilepsy in children. The device detected sudden changes in noise intensity above the child's background level and produced an aural stimulus which, after conditioning training, was successful in suppressing reflex seizures.

The Suppressive Device: At the onset of a petit mal seizure, the child's electroencephalogram (EEG) contains a characteristic waveform sometimes referred to as "spike and wave" pattern. A prototype device has been developed to detect this characteristic slow wave activity of the abnormal EEG and thus determine when a seizure occurs. The EEG is obtained from electrodes placed behind the ears and fastened to eyeglass frames. This is done to make the electrode array as unobtrusive as possible to permit use of the sensory system continuously in a child's normal environment. To date silver/silver chloride electrodes have been used, but capacitantly coupled electrodes being developed under contract to JSC will be evaluated as soon as prototypes are available. These sensors, if successful, would greatly enhance the suppressive system potential use due to simplified

sensor fixation and freedom from site preparation and electrode cleaning. The electronic module would be of a small size suitable to be worn on a belt or in a shirt pocket. A micropower EEG amplifier developed by Ames Research Center is utilized. The principle of detection of the abnormal EEG depends on two parameters: (1) the number of slow waves of a particular frequency band within a time interval, and (2) the amplitude of the slow waves, which is typically twice that of normal EEG amplitude. Each criteria must be individually tailored to each child for optimum results. Once the seizure is detected, an auditory signal to which the patient has been conditioned, is delivered to the child by an earphone. Preliminary laboratory studies have shown that delivery of an alerting stimulus directly after onset of seizure activity may interrupt propagation and suppress the seizure. Additional outputs for functions in addition to therapy could be a signal also sent to the teacher in the classroom to enable identification of the child's seizure, and an intrinsic or external recording mechanism to record the number and frequency of seizures to both evaluate the therapeutic mode of the audio feedback, and additionally, the effectiveness of drug therapy.

The prototype device has been evaluated using magnetic tape recordings from children during petit mal seizures. Additionally, clinical tests have been conducted on patients at the Neurological and Rehabilitation Hospital, which is associated with the University of Wisconsin-Madison. Functional testing to date, both on patients and with the recorded tapes, has demonstrated reliable recognition of the slow wave activity associated with seizure onset, and a high degree of rejection of noise and other artifacts for the device. False positives were very minimal after adjustments to the individual's characteristics were done.

In order to help determine the market potential for the petit mal suppressive device, a product concept test was undertaken by the Biomedical Applications Team in conjunction with the Bureau of Business Research and Service of the Graduate School of Business Administration, University of Wisconsin-Madison. The concept test consisted of a mail questionnaire which was sent to a random sample of 400 neurologists throughout the United States. The questionnaire assessed the physician's opinion of the merit of the general product idea, the worth of the device as a therapeutic and diagnostic tool, the physician's reaction to some contemplated selling prices, and solicited the physician's general comments regarding development of the described device. The majority of the neurologists responding to the questionnaire perceived the device, if clinically validated, as having significant diagnostic and therapeutic benefits for the petit mal patient. The majority expressed interest in recommending the device for use by their patients if it were commercially available. Subsequently, a market study of the petit mal suppression device was conducted by the IIT Research Institute in Chicago, Illinois. This study concluded that there were significant disadvantages to the chemotherapy presently used to suppress petit mal seizures in children, and that it was the perception of clinicians that a functionally operable electronic device would have desirable features if cost factors were not extreme. The IITRI report estimates that over the next five years, a clinically validated suppressive device would find use by more than 37,000 petit mal patients in the United States. They also indicated that a significant need existed for diagnostic units of more flexibility, and that approximately 7,000 of these units would be needed over the next five years. Additionally, the IIT Research Institute estimated there may be other applications for a device of similar technology for measurement

of onset of sleep or loss of attention in hazardous occupations such as truck drivers, railroad personnel, defense applications, and others.

Current Activity: A petition for waiver of rights to this invention on behalf of the Wisconsin Alumni Research Foundation (WARF) was filed, as well as on a patent application. Unfortunately, between the date of application and the time of review by the Patent Office, a new patent was issued on a similar concept. This could not be identified during the pre-application investigation as it had not been issued. The newly issued patent covers some of the concepts developed in UW-6, although not employing artifact rejection circuitry to reduce false detections. The existence of this similar patent, however, increases the likelihood of an interference and attendant litigation. These factors reduce the attractiveness of early involvement by commercial interests in the device product concepts. Consequently, the request for waiver of rights has been withheld and this project has been moved to holding status with respect to BAT priority.

Research is continuing by two medical investigators, however, to further explore the utility of the concept and gather more data to determine if further development is warranted. Dr. Ruggero Fariello of the Neurological and Rehabilitation Hospital will use the monitoring device on selected petit mal patients. Additionally, in a separate research program at the University of Arizona Medical Center, funding has been secured to replicate the petit mal monitoring device. Dr. Philip Walson will conduct this investigation, a collaborative effort between the departments of Pediatrics and Pharmacology to assess drug effects in children with petit mal disease.

Problem Investigator: Dr. Charles S. Cleeland, UW Department of Neurology.

BATeam Coordinator: James C. Houge.

Problem UW-10 - Coating for Chronically Implanted Devices Impermeable to Water Vapor

Help Wanted: Commercialization sources.

The Need: An easily applied coating, impermeable to water vapor for plastic encapsulated implanted electronic devices.

Background: Nearly all electronic assemblies presently used for chronic implant, notably cardiac pacemakers, are encapsulated in epoxy resin with an overcoating of silicon rubber. While this is a biocompatible packaging configuration, both the silicon and the epoxy have relatively high rates of water vapor permeation. After a somewhat viable time period, this results in the electronic circuit operating in a 100% relative humidity environment. Any contaminants on the electronic assembly left during the fabrication, if containing any ionic material, will result in corrosion, shunting of the electronic circuit, and erratic operation or failure of the assembly. Some newer designs are totally encased in a metal or ceramic case which is hermetically sealed to circumvent this water vapor permeation problem. This, however, is a relatively expensive and exacting process which adds to the cost of the device. If a glass or metal coating which would be impermeable to the water vapor could be applied to a plastic encapsulated electronic assembly, it might be possible to achieve the same degree of protection to the circuitry at a reduced cost and simplified processing of the assembly.

Present Status: A specific application problem for environmental sealing was posed by Professor Paul Bass of the Department of Pharmacy and Pharmacology at the University of Wisconsin. Professor Bass is developing instrumentation to measure rate of flow from the stomach into the small

intestine of dogs. He is attempting to use a thermo-anemometry technique utilizing glass microbead thermistors attached to a microminiature teflon-jacketed cable. Environmentally protecting the thermistors and associated electrical connections in a thin and highly conforming durable coating has been very difficult to date using commercially available conformable coating materials. The intended result of this investigation would be a clinically usable device to assess stomach emptying in humans. Contact was made with Dr. Ted Wydeven at NASA Ames Research Center, and an agreement was reached to coat samples using this plasma coating process developed at Ames for halide lenses for evaluation by the UW-BAT.

The evaluation program was proposed as an adjunct to the ongoing Ames RTOP which has not yet begun, as this program has not yet been funded. In the interim, samples will be coated by Dr. Wydeven and tests conducted by the UW-BAT to quantify the water vapor permeation rate. The level of this parameter will indicate whether promise exists for an implanted vapor barrier. Successful evaluation would likely result in commercial interest by several manufacturers, including Ohio Medical Products, who has contacted the BAT in search of such a coating.

Problem Investigator: Dr. Paul Bass, UW Department of Pharmacy and Pharmacology.

BATeam Coordinator: James C. Houge.

Problem UW-15 - Wide Area Medical Communications

Help Wanted: Commercialization possibilities.

Abstract: The provision of physician background is important in the optimization of on-site emergency care but is difficult to provide outside urban areas. Needed is a method for providing reliable automatically controlled medical communications between an emergency medical technician and a hospital beyond direct radio range.

Background: One of the most significant aspects of quality emergency medical service (EMS) is the provision of on-site emergency medical assistance by trained emergency medical technicians (EMTs). An important element in maximizing EMT effectiveness is the availability of physician advice during pre-hospitalization care of the emergency patient. However, the advice must be directly and reliably available on a 24-hour basis. Unfortunately, outside of urban areas, hospitals are generally unable to staff emergency rooms with physicians on a 24-hour basis. This need for physician backup is particularly crucial in EMS systems utilizing volunteer EMTs who see duty infrequently and find it difficult to maintain a high level of experience and proficiency.

Many states have existing statewide microwave systems which could probably be used for EMS on a shared basis. EMTs statewide could then gain access over the microwave system to medical backup. In most such potentially shared systems, the dispatchers and controllers have primary responsibilities other than in EMS. Moreover, channels reserved for medical communications require a high degree of reliability even though they might be infrequently used. Thus, in order to be practical, shared

use of a system must be automatically controlled and channel usability continuously monitored. It would appear possible that by means of automatic channel control and monitoring equipment, an EMS vehicle would be able to communicate directly over a shared microwave network with a physician at a major medical facility having 24-hour, in-house physician coverage.

There presently exists in Wisconsin a statewide, high band VHF communications system for EMS which utilizes transceivers on 22 microwave towers providing coverage for over 95% of the area of the state. With this system, an ambulance can contact a dispatcher at one of seven area state patrol headquarters. However, the system as presently configured does not provide for medical communications. A communications channel monitor designed under contract to Kennedy Space Center (NASA Tech Brief 67-10028, entitled "Monitor Assures Availability and Quality of Communication Channels") has been identified as applicable to the solution of this problem. Moreover, it appears that slight modification of this circuitry would not only allow channel monitoring, but also provide the required control function to selectively bypass the state patrol dispatcher and allow communications directly with hospital personnel.

Progress to Date: One of the 22 state patrol microwave towers has been selected as a site for tests of a prototype system using this NASA-developed system concept. The selected tower site is located near Baraboo, Wisconsin. The Marquette County EMS system has expressed a particular interest to participate in operational tests of the prototype system, in view of their present inability to obtain 24-hour physician backup. Preliminary radio coverage tests have indicated that the entire Marquette County area is within radio range of the Baraboo tower. University

Hospitals, Madison, Wisconsin, will provide the medical backup. Design of the prototype system has been completed. Necessary system components have been obtained and assembled. It was possible to assemble the monitoring equipment required at the hospital terminal on circuit boards which could fit into a commercially available communications console (see Fig. 1).

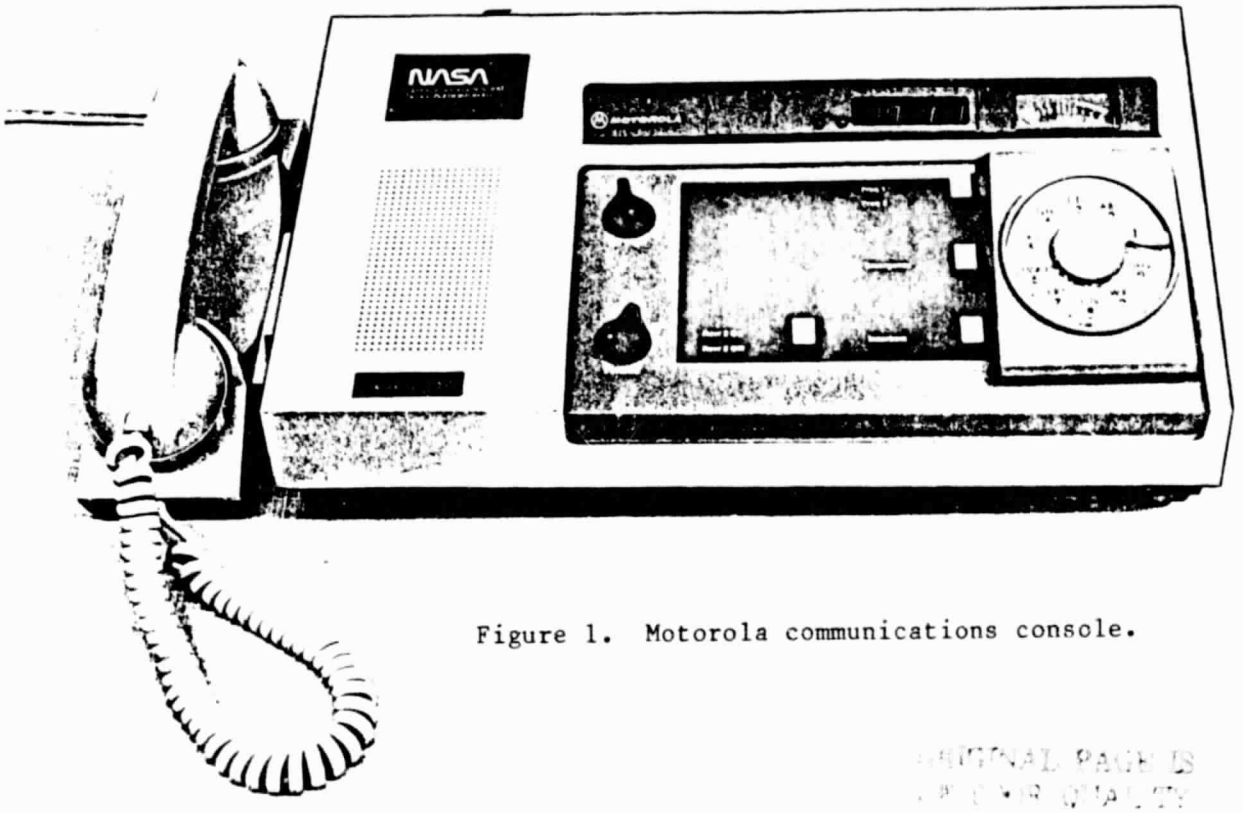


Figure 1. Motorola communications console.

Implementation was initially hampered by incomplete documentation of the existing microwave system. Some fears were also expressed by the hospital administration as to imposing additional pieces of hardware upon medical personnel without adequate human factors engineering of their total communications system. The problem is complicated by the fact that the local paramedical communications system has been recently redesigned. Operational testing of the system has been additionally delayed as a result of a reliability problem discovered in the state EMS network. State radio personnel are currently analyzing the microwave control network which has

been found to be intermittent in operation. This problem has probably been present since the initial installation of the system over two years ago, but was not discovered until testing of the NASA channel quality monitor was undertaken. It was anticipation of this type of problem with low usage channels on shared communications systems that indicated a need to automatically and continuously monitor channel patency. While the UW-BAT role in this test program has been essentially completed, completion of the operational testing has been delayed pending resolution of the problem discovered in the basic microwave control system.

In spite of the delay in the start of testing of the prototype system, a great deal of interest has been expressed by health planners from around the state. Proposals for development of wide-area medical communications based upon the NASA-sponsored prototype system have been included in three regional health planning grant applications for implementation funding under Section 1203 of Public Law 93-154 (Emergency Medical Services Act of 1973). These applications cover 31 of the 72 counties in Wisconsin. In addition, the state level 1203 grant application included funding to develop a design and draft specifications for a statewide wide-area medical communications system based upon the results of the prototype evaluation.

External Program Contributions: The Wisconsin Division of Health has committed staff time and mobile equipment to the program. The use of the state microwave network has been authorized. Additionally, the Marquette County Emergency Medical Services system will participate in the operational tests. University Hospitals in Madison will fill the role of providing 24-hour-per-day physician backup.

Commercialization Potential: Other channel quality monitoring devices are commercially available and in general use for telegraph and digital data circuits. However, they are not designed to monitor channels carrying voice or other signals that contain many random frequencies. Also, they cannot monitor all the critical parameters of voice and high-speed data circuits. The communications channel quality monitor developed under NASA sponsorship has both voice and high-speed data capabilities.

Assuming successful demonstration of the prototype system, it is anticipated that functional specifications for a monitoring and control module will become a part of the system proposed for implementation under the recently submitted grant applications. Following regional application, the same system requirement would be included in statewide planning. Replication of the monitoring and control module requirement in other regions would likely occur.

Several states have in service or are planning the use of microwave systems for EMS on a shared basis. Moreover, numerous law enforcement agencies utilize communication channels in a parallel manner to this EMS usage. Commercialization potential is enhanced by the possible inclusion of channel quality monitoring requirements in the specifications for new public service communication channels.

Problem Investigator: John L. Hankes, EMS Planning Analyst, State of Wisconsin, Division of Health Policy and Planning.

BATeam Coordinator: Everis R. Engstrom.

Problem UW-23 - Conformable and Autoclavable Return Electrode for Electrosurgery

Help Wanted: Commercialization sources.

The Need: A conformable return electrode to make reliable and safe contact over a large skin area. This would eliminate the possibility of exit burns and ensure more consistent electrosurgical procedures.

Background: Electrosurgical dispersive return electrodes are normally supplied in the form of flat stainless steel plates. This configuration is convenient to place, easily cleaned and steam sterilized. When used for human electrosurgery, deformation of the buttock normally permits sufficient contact area to minimize heating due to current passage. Flexible foil, pre-gelled, disposable return electrodes are available, which may be wrapped around a limb to establish low resistance contact. These electrodes are significantly more expensive than the reuse of a permanent autoclave sterilizable return electrode.

Another aspect of the return electrode problem is that of research involving small animals such as rats and small dogs. The sharp body contours of these animals make establishment of a low resistance, large area body contact for RF current very difficult. A conforming return electrode would have potential benefit for both human surgery and for animal research.

Present Status: Return electrodes capable of withstanding repeated autoclave sterilization and flexible enough to closely conform to body contours were fabricated from high temperature silicone elastomers, filled with conductive particles. Materials and suggestions were provided

by Dr. Salvador Rositano of Ames Research Center. Materials included silicone rubber filled with carbon, silver flake, and silver plated glass microspheres. The electrode sheets were approximately 10 cm x 10 cm and 2 mm thick (see Figure 1). Comparative evaluations were performed between the conductive elastomeric return and a stainless steel plate electrode after five steam sterilization cycles. Both cut and coagulate modes were conducted using both organ (pork liver) and muscle (rat) tissue.

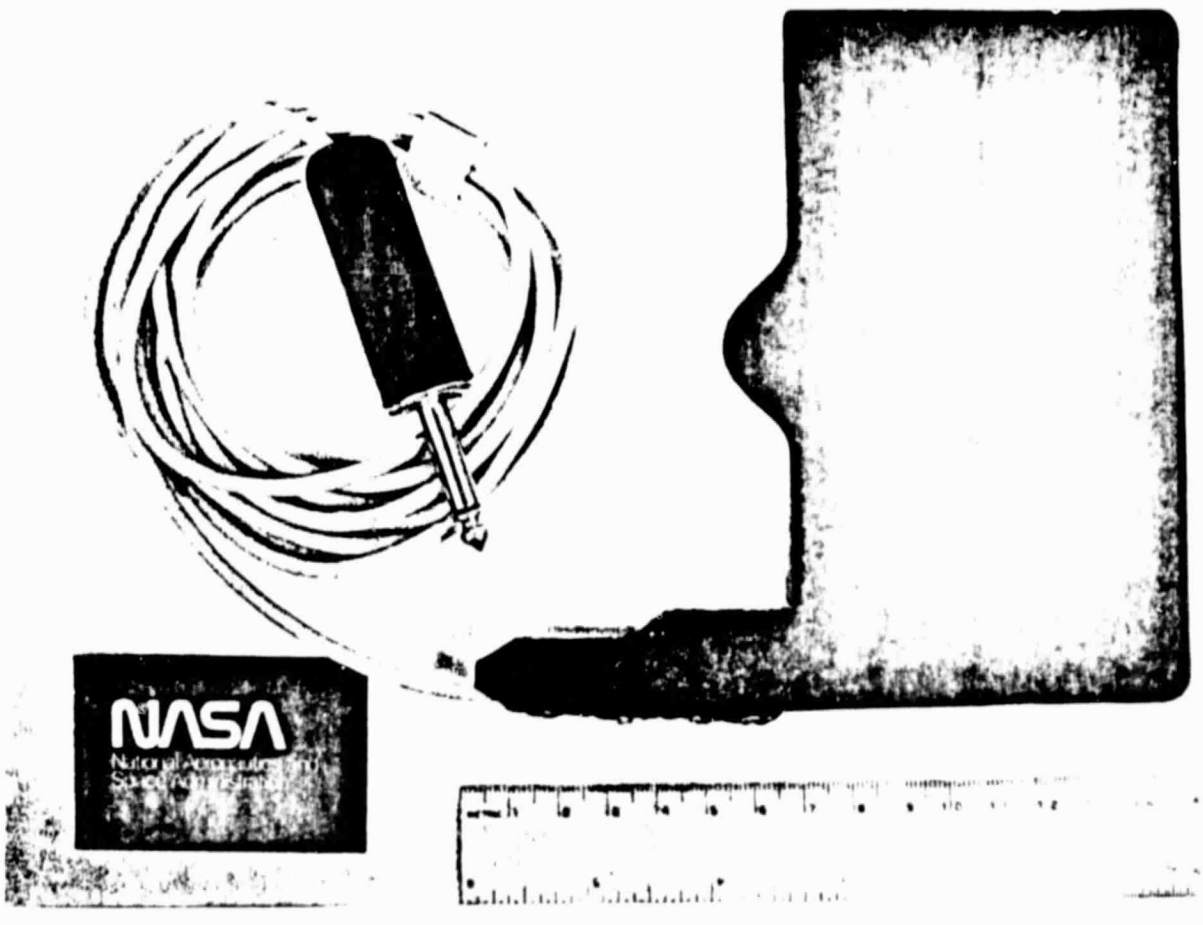


Figure 1.

A solid state electrosurgical generator was utilized, and the active electrode for all procedures was a 2 mm x 15 mm blade. No significant difference was discernible for either cut or coagulation in power required to achieve satisfactory technic with several investigators executing both procedures. Clean cuts and comparable rates of coagulation were demonstrated at similar power levels for both return electrode types.

An invention disclosure has been filed on this electrode design and transmitted to NASA Headquarters. Contact has been made with two companies who have expressed potential interest in development and marketing of a product utilizing conductive elastomeric material. Both Cameron-Miller of Chicago and In Vivo Metric Systems of Redwood City, California have indicated that further test data and a more detailed cost analysis will be necessary to their decisions about participation in commercialization of the concept. Tests of comparative tissue interface impedance with various configurations will be conducted first quarter of CY 1978. Two vendors capable of compression molding the conductive elastomer have been contacted and will provide price quotations on fabrication costs for the electrodes to complete the information package.

Problem Investigator: Charles E. Yale, UW Department of Surgery.

BATeam Coordinator: James C. Houge.

Problem UW-24 - Automated Patient Tracking System

Help Wanted: Identify applicable NASA technology.

The Need: A hardware/software system is needed to gather data on the flow of patients through an ambulatory care clinic and other restricted settings.

Background: That health care is growing increasingly complex, costly, and in many cases inefficient, is an oft-repeated truism in America today. One solution to the problem lies in the application of new or improved management techniques to the medical clinic. Whenever a system is changed, however, it is prudent to have available an objective means to evaluate the system before and after the change.

In the case of a medical care system, virtually all studies undertaken for analytical, planning, or evaluation purposes depend upon manual methods of data acquisition. These are largely of two types: forms, including the medical records in normal use, and observations made by trained observers. In both of these, human factors can severely restrict the completeness, accuracy, availability, and continuity of the data being acquired.

Specific Focus: The investigator has taken part in discussions leading to a project in which JPL conducted analytical and modeling tasks for the UW Department of Family Medicine and Practice. The overall purpose of the project was to improve patient care being delivered in family practice clinics by optimally configuring space and procedures in the clinic. It is believed that the management control being sought can also be applied to other primary care facilities.

An important aspect of the concept, both in terms of validation of the model as well as the general applicability of the results, is the need for data describing patient flow. Present plans call for the acquisition of these data using one or both of the manual techniques described above. The use of automated data acquisition methods, however, appears to be feasible and offers many advantages. Among these would be accuracy, continuity, and greatly decreased interference with ongoing medical activities.

BATeam Activity: The need is for a system to track and document the passage of patients through a primary care facility. Two major impediments to the implementation of an APT system are (1) more precise information on what data are needed and how the results would be used, and (2) funds to set up a prototype system. We are investigating NASA sensor technology, computer software, display equipment, etc., but there is no provision, at the present time, of adequate funds to design, build, and test a prototype APT system.

The design concept would be to place either sensors or special reading devices at locations throughout the clinic. The former would operate entirely without human assistance while the latter would require the patient to feed an ID card of some sort into the readers sequentially as he passed through the clinic. A minicomputer would receive signals from the sensors/readers on-line, store the event and provide for management interaction at any time.

Progress Summary: A biomedical engineering student at UW-Madison has carried out a small-scale investigation of problems associated with gathering data on patient flow in an ambulatory clinic. His data acquisition system

required the manual entry of times and events on computer cards which were subsequently optically read into a computer. He found that clinic employees accustomed to routine, such as the receptionist, could provide sufficiently accurate data after a short practice period, but health care providers, such as nurses and physicians, either would not or could not comply with the data acquisition requirements. Thus, patient flow data could not easily be obtained for much of the course of the visit. The pace and dynamic character of the patient/provider encounter, coupled with the priority of delivering health care over efficient management, made the data acquisition system relatively useless. This result confirmed the hypothesis that the acquisition of patient flow information must be automated to be effective.

Further study of the needs of such a system is needed so that specific requirements can be stated. The need appears to be very broad since most health care, measured in terms of patient encounters, occurs at the primary, or first contact, level of care. Besides general applicability in the health care system, a data acquisition system that monitors the whereabouts of people in other restricted settings, such as nursing homes, might yield savings and increase effectiveness.

Since the Team is committed to finding ways to transfer NASA technology to the service of primary care needs, further work on this problem statement is anticipated. Our attention to the problems of the aged also suggests the need for continued attention to the subject of this problem statement.

Problem Investigator: Dr. John H. Renner, Dept. of Family Medicine and Practice, University of Wisconsin-Madison.

BATeam Coordinator: William N. Fetzner.

Problem UW-30 - Multi-Spectral Analysis of Tissue Viability

Abstract: There exists a need for a surgeon to noninvasively determine the optimum level of amputation on patients with drastically impaired circulation of the limbs. The Jet Propulsion Laboratory has modified a NASA computer-enhanced optical process and is presently using it to aid physicians in the diagnosis of burn patients. This technique may have applicability to the amputation problem.

The Need: According to Dr. James S. Keene, Assistant Professor, Division of Orthopedics (under joint appointment with the VA and University of Wisconsin hospitals, Madison), the specific level of amputation chosen in patients with ischemic changes is generally based upon the judgment and experience of the surgeon. Dr. Keene believes presently available objective criteria such as level of distal pulse, skin temperature and angiographic patterns of disease have not proven to be reliable predictors of eventual amputation healing, and that a system capable of quantifying skin and muscle blood flow could better predict successful levels of amputation.

Background: Dr. Victor Anselmo of the Jet Propulsion Laboratory has been primarily responsible for the development of the computerized burn analysis system presently in use at the University of Southern California Medical Center. Two systems have been developed, one employing conventional 35 mm photographic techniques, and the other using a specially designed scanning camera head. The photographic system, as originally configured, operates as follows.

Three conventional 35 mm SLR cameras simultaneously photograph the burn area through three optical filters: near infrared (Kodak 89A), yellow-green (Hoya "X-1"), and red (Hoya 25A). The films employed are

high speed infrared, and "plus X," both commercially available black and white films. Two additional cameras are used without filters to photograph the burn area, both in black and white and in color. These latter photographs are used for comparison and reference only. The photographs are taken in a darkened room using an inexpensive Xenon strobe light. The black and white photographs taken through the three filters are then scanned by a high resolution optical system at JPL, and each point on the photograph is assigned a number (quantitized) on a gray scale. These digital values are fed into a computer. The computer software registers the photographs to correct for parallax, and then computes three ratios for each point: red to yellow-green, infrared to yellow-green, and infrared to red. The ultimate output is a color-coded print of the burn area that shows partial-thickness burns as blue regions, partial-to-full-thickness burns as red, and full-thickness burns as yellow-green.

The system presently undergoing clinical trials at the USC burn ward utilizes a camera head with a planar scanning mirror to sequentially optically transmit the burn image to three filters backed by linear photo-diode arrays. The information is digitized, processed by a mini-computer and ultimately appears on a color TV monitor. The display format is similar to the pseudo-color picture obtained using the previously described photographic system.

The multispectral analysis technique employed by these two systems essentially maps the hemoglobin oxygenation of subcutaneous vascularization to a depth of 3 to 4 mm. It vividly contrasts zones of hyperemia, stasis, and coagulation, and should enable the surgeon to determine at an early stage those areas that will require skin grafts in order to heal.

Progress - Application to Peripheral Vascular Disease Diagnosis: To determine the applicability of the multi-spectral analysis techniques to peripheral vascular disease diagnosis, two patients with peripheral vascular disease were photographed at the VA Hospital in Madison by Dr. Anselmo of JPL. The photographs were taken through a series of optical filters both prior to, and following, application of radiant heat to the affected limbs (dilation of the surface vasculature due to increased skin temperature accentuates the effect of any vascular flow restrictions). Pressure profile recordings of the affected limbs were also taken under the same conditions using an occlusive cuff (non-invasive) measurement system. Brief medical histories of the two patients are as follows:

(1) Patient A suffers from bilateral leg pain after walking several minutes, has a history of hypertension, and due to poor circulation has undergone amputation of the left great toe. Pressure recordings and arteriography suggest local inflow obstruction of left iliac system.

(2) Patient B, a diabetic, was recovering from burns on the calf of one leg. The burn had been incurred by overexposure to the radiant heat from a wood-burning stove, and had been aggravated by prior frostbite of the area.

The photographs taken at the VA Hospital were analyzed at JPL, and the results conveyed to Dr. Turnipseed at that hospital. There were pronounced differences in the spectral reflectance characteristics between the diseased and more normal areas of tissue for both patients. While it was not possible to determine the optimum filter types for most effective differentiation due to the limited data, both Dr. Anselmo and Dr. Turnipseed were encouraged by the findings and felt that further controlled studies of patients with

peripheral vascular disease using the JPL/NASA processing technique were warranted.

Progress to Date: A meeting has been scheduled with Dr. Turnipseed at the VA Hospital for mid-January 1978 to discuss specific methods of applying the JPL/NASA multispectral analysis techniques in studying several patients with peripheral vascular disease. An evaluation of this technique will be coordinated with other approaches proposed by the VA Hospital in Madison for vascular disease diagnosis.

Problem Investigators: Dr. James J. Keene, Dr. William Turnipseed, and Dr. Theodore Goodfriend, VA Hospital, Madison, Wisconsin.

BATeam Coordinator: L. Burke O'Neal.

Problem UW-32 - New Femoral Head Prosthesis Design to Improve Long-Term Stability

Help Wanted: Identify interested companies.

Abstract: Femoral head prosthesis failure has proven to be a clinically significant problem. Host rejection of cement, loosening through bone resorption and fatigue failure of the stem due to loosening are major modalities of failure. A new design has been proposed to solve these problems, but needs further investigation.

The Need: "Today we are still living in the revolutionary era of total hip replacement, a worldwide revolution in which about 20,000 orthopaedic surgeons are more or less involved and nearly 1 million patients are personally involved. There is such enthusiasm that now some surgeons are performing total hip replacements in patients under 50 years of age."[1] A recent market study shows that just the West European market for implant devices for long-term use was $280 million in 1975, projected to increase to $430 million by 1980.[2] In spite of the vast number of total hip replacement procedures performed around the world, pioneers in the field such as Maurice E. Muller and John Charnley acknowledge the fact that late complications and failures of the femoral head component are clinically significant. Patterson and Brown[3] have reported an incidence of 31% major complications in the first two years after total hip replacement. Total hip procedure became popular in the United States only after 1965, as opposed to 1958 in Europe. The recent statistics from Europe indicate that today there are as many procedures redone in Europe as there are new cases.

One mode of failure is fracture of the stem. In all cases of such fracture, loosening of the proximal half of the stem is observed.[1]

Another cause for loosening may be allergy or host rejection of methylmethacrylate cement (0.5% of cases), used to bond the prosthesis to bone. This takes place within 1 year following the operation.

The main complication, however, is loosening after 5 years. To understand the loosening problem, we have to know that no real bond can occur between bone and cement. A fine layer of fibrous tissue always will develop between cement and bone, thus permitting some movement between the elastic bone and the rigid cement. If the medullary cavity is not fully packed or if the bending forces are too great, for example, in a prosthesis fixed in a varus position, the movement at the interface between cement and bone will soon increase. This will lead to bone resorption, fibrous tissue formation, and gradual loosening of the femoral stem in the first years following a total hip replacement.[1]

Specifications: A new design of a femoral head prosthesis has been proposed which would offer improved long-term stability.

Actions Taken:

Patent Status of the New Design: The femoral head prosthesis design was reported to the contract monitor, Mr. Don Friedman, under the "New Technology" clause of the contract. Subsequently, a decision was made by the Wisconsin Alumni Research Foundation (WARF), a non-profit patent management organization that represents the University of Wisconsin in patent matters, to file for a waiver of rights to the invention. The premise for the waiver application was that WARF and the University of Wisconsin then would practice and commercialize the invention using their own resources. Through a letter dated October 25, 1977, the Board of Regents of the University of Wisconsin System were informed that the NASA Inventions

and Contribution Board had recommended to the Administrator that the petition be granted (Waiver No. W-1876). Notification of action by the Administrator on the waiver has not been received as of this date.

NASA Technology: Substantially relevant NASA technology was located at the Ion Beam Applications Section, Space Propulsion & Power Division of Lewis Research Center (BAT quarterly report July-Sept. 1977). It appears that the ion-beam technology could be used to fabricate the porous polymer sheath which is the unique feature of the proposed design. A January meeting has been planned with Mr. Bruce Banks, Head of Ion Beam Applications Center and Paul foster, TU officer at Lewis, to discuss feasibility of this technology application.

Commercialization Plans: After the waiver notification is received, an invention application will be filed by WARF. Companies in the orthopaedic implant business will be contacted according to commercialization strategy jointly developed with WARF.

References

1. Maurice E. Muller, Late Complications of Total Hip Replacement, Proceedings of the second open scientific meeting of the Hip Society, 1974, p. 319.
2. Market Survey Available on Polymers in Medicine, Biomedical Technology, August 23, 1976, p. 76.
3. Patterson, F.P., and Brown, C.S., The McKee-Farrar Total Hip Replacement, J. Bone Joint Surg., 54A:257, 1972.
4. J.J. Klawitter, et al, An Evaluation of Bone Growth into Porous High Density Polyethylene, J. Biomed. Mater., Res. Volio, p. 311-322, 1976.

Problem Originator: Dr. James Keene, VA Hospital, Madison, Wisconsin.

Problem Investigator: Dr. Andrew McBeath, Assoc. Prof. and Chairman, Division of Orthopaedic Surgery, University of Wisconsin Hospitals.

BATeam Coordinator: Bakki V. Kudva.

Problem UW-33 - Miniaturized Force Transducer for Gastrointestinal Motility Studies

Help Wanted: Size of market, possibility of developing standard configuration, identify custom manufacturer.

Abstract: Needed is an implanted, miniaturized force transducer suitable for monitoring the force of contraction of individual contractile segments of the small bowel of unanesthetized animals for periods of at least six months. Various transducers which may be applicable have been developed by NASA and are being investigated for possible application.

The Need: Several patterns of gastrointestinal tract smooth muscle contractile activity, referred to as motility, have been described. Specific patterns of motility have been associated with pathologic states such as diarrhea and constipation. Because intraluminal devices and anesthetics can markedly affect motility, extraluminal force transducers which may be used to monitor contractile activity in the gastrointestinal tract of unanesthetized animals have been developed. Currently used transducers are approximately 1.5 cm long, 0.7 cm wide, and .3 cm thick. In the small bowel of the dog, the length of an individual contractile segment is approximately 1 cm. In order to define the pressure-flow relationship in the intestinal lumen, it is necessary to determine the contractile profile within an individual contractile segment. What is needed is a miniature force transducer which will allow determination of the contractile profile of an individual, 1 cm long contractile segment.

Specifications: The width is the critical parameter. Ideally, a width of 1 mm or less is desired. The length should be 1 cm or less. Forces to be measured are 0-100 g.

Actions Taken: A computerized search of the NASA data base has been completed. Known relevant NASA technology is being evaluated for possible application. A NASA-patented miniature catheter tip force transducer (Patent 3,971,364) developed at JPL may be modifiable for this use. The possibility of obtaining some prototypes from JPL for evaluation by the problem originator is being investigated. Also, an attempt is being made to determine if a significant number of other researchers would be interested in strain gages of this configuration. If that proves to be the case, commercialization efforts may be worth pursuing.

Problem Originator: James Christensen, M.D., Director, Division of Gastroenterology, University of Iowa.

BATeam Coordinator: Everis R. Engstrom.

Problem UW-34 - System to Provide Quantifiable Vestibular Stimulation and Motor Response in Children with Delayed Development

Help Wanted: Methods for vestibular assessment for children.

Abstract: The methods used presently for clinical evaluation of developmentally delayed children and for the provision of vestibular stimulation for therapy are predominantly manual, quite subjective, and result in considerable scatter. The development of means for quantifying both the input vestibular stimulation and more exact measurement of motor performance would be of significant value in the clinical setting.

The Need: Some children experience developmental delay as a result of sensory deprivation caused by slow maturation, coupled with inadequate responses of the sensory and motor systems to environmental stimuli. Therapeutic intervention to counteract these delays normally take the form of sensory enrichment programs. Physical and occupational therapists working with developmentally delayed children use developmental behavior patterns including specific postures that involve the child's nervous system in stimulus, integration and response. An operational hypothesis is that a specific vestibular (occurring in the semicircular canals of the inner ear) stimulus applied over a specified period of time will effect an improvement in motor performance. The parameter most often used as a measurement of vestibular response is the degree and interval to acquire nystagmus (an oscillatory eye movement) habituation due to vestibular stimulus.

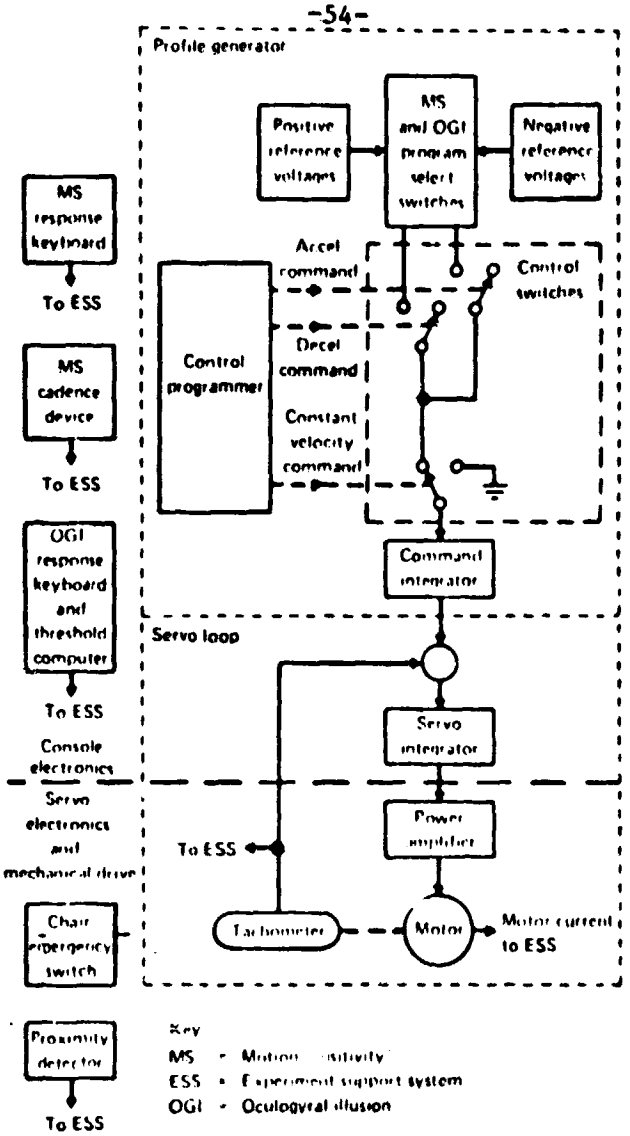
Specifications: Stimulus to the vestibular apparatus is most often achieved by rotating the child either manually or on a rotating platform.

Variation of the inclination of the specific pairs of semicircular canals, combined with differing angular velocities, accelerations, and decelerations, are used to provide varying input stimulus. Probable speed range required would be in the order of 20-40 rpm, with capability of up to two feet off-center displacement would initially be desirable, with the capability of fixation of varying degrees of angulation of the child's head to provide varying stimulation. Ideally, the capability for speed variation or other means to provide elliptical movement or multiple cycles of acceleration/deceleration per revolution might be clinically useful. The capability of self-control and braking to terminate unpleasant experience by the child would also be desirable for older children. Instrumentation to record the EOG and EEG might provide more quantitative measures of motor performance than visual observation of subject eye movement during rotation.

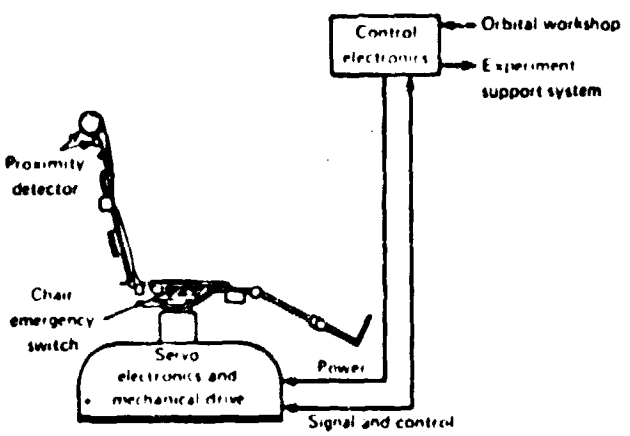
Actions Taken: A literature search has been initiated to identify work done by NASA including measurement of astronaut response to acceleration and deceleration and centrifuge setting to identify potentially applicable NASA technology and/or methodology. Information on vestibular assessment programs for both the Apollo crew and in-flight tests done on Skylab have been given to Professor Punwar for review.

The Rotating Litter Chair developed at Johnson Space Center and used in Experiment M131 on Skylab incorporates all of the necessary features for a system for vestibular assessment of children. It is probable that a device intended for therapy could be a simplified version of the litter chair.

Collaborative support for the initial phase of specification development and functional definition has been obtained from non-NASA sources. A prototype device was fabricated and will begin evaluation in January 1978. Results of these tests should provide the basis for better functional



Simplified functional block diagram.



Simplified interconnection diagram.

Rotating Litter Chair Used on Skylab Orbital Workshop

definition of required system parameters and permit development of a product concept and commercialization plan.

References:

1. "Environmental Modification of Autistic Behavior," Ornitz, A. Arch. Gen. Psychiat.:22, 560-565, 1970.
2. "A Disorder of Sensory Motor Integration," Infantile Autism Concepts, Characterization, and Treatments, pp. 50-68, London, 1971.
3. "Effects of Vestibular Stimulation on Nystagmus Response and Motor Performance in the Developmentally Delayed Infant," Kantner, R., et. al. Physical Therapy, 56:4, 414-421, April 1976.

Problem Originator: Alice Punwar, Director, Occupational Therapy Program, UW-Madison.

BATeam Coordinator: James C. Houge.

Problem UW-35 - Portable Dental Equipment

Abstract: A need for portable, modular, dental equipment has been identified by the UW-BAT to deliver dental care in rural areas here and abroad, and to provide such care to armed forces personnel on active duty, handicapped children, chronically ill adults and prisoners. A similar need exists in public dental health programs to conduct preventive dental care clinics for the underprivileged youth population. There seems to be a potential for transfers from different areas of NASA technology and expertise.

The Need: Traditionally dentists have been confined to their offices and bulky fixed equipment. There is no commercially available portable dental instrumentation system. As a consequence, that fraction of the population who cannot visit the dentist on a regular basis (due to various reasons which will be discussed later) just do not have any dental care available to them.

Even here in the United States, the lack of dental care is one of the most critical health care problems of rural people.[1] The link between sound oral health and proper nutrition has gained importance only recently. Early loss of teeth or infected gums will disable a person to chew, hence, causing malnutrition even in an area where there is an abundance of good food.

A review of existing literature shows an alarmingly high number of people in this country alone who do not receive dental care of any significance. The people lacking dental care can be classified into the following categories.

Indigents: In New York City, an estimated 200 000 children (6-14 years) receive only minimal care such as emergencies and extractions.

Handicapped Children and Chronically Ill Adults: Due to long neglect and debility through illness, these people have very poor oral

health status. A DHEW study in Kansas City showed that 7,000 people as being homebound.[5]

Institutionalized: There are 880,000 persons in mental hospitals, prisons, and other institutions who get only minimal care.[2]

Since the inception of the Social Security Act of 1935, dental divisions of the State Health Departments grew from 13 to 50. The dental divisions are operated by grants from Social Security. In the past there have been two approaches in catering to the needs of these people:

(a) Fixed location clinics and bussing of people to these clinics.

(b) Mobile clinics.

Both methods are expensive. Bussing people in communities larger than 40,000 is very laborious.[3] A mobile clinic currently costs about $60,000.

Thus, a lightweight, portable, easy to set up, modular dental system with a price tag around $10,000 would use the federal funds efficiently and provide dental care to more persons for the same dollar value.

One other factor contributing to this lack of dental care has been unavailability of manpower for such operations. The new Health Manpower Act of 1976 promises to alleviate this problem. The bill authorizes capitation grants of $2,050 average per full time dental student for fiscal year 1978 through 1980. The conditions for award of such grants to dental schools are that "schools must either increase first year enrollment over that in 1976-77 by 10% or have an approved plan to train all students prior to their graduation at least six weeks in ambulatory care settings in areas remote from main teaching site or in areas in which medically underserved populations reside."

To gain a better insight into this problem area, the UW-BAT conducted a telephone survey by contacting 11 prominent dentists across the country

and two leading manufacturers of dental equipment for their opinions and experiences (see list at end of this problem statement).

A breakdown of their opinions is as follows:

(a) All persons contacted agreed that there was a definite and urgent need to deliver dental care to the kinds of people discussed above.

(b) All agreed that it would be worth our while investigating the possibility of putting together a miniaturized total dental system using aerospace technology.

(c) Everyone concurred on their opinions that the past and current lack of demand for such equipment is due to manpower shortages and funding deficits.

(d) Nine persons, including the two manufacturers, were of the opinion that demand for such equipment would grow in the next 5-10 years through increases in manpower and in financial grants.

(e) Two of the dentists had no opinion as to the future of portable equipment.

(f) Two other dentists thought there would not be a substantial demand for portable equipment, but qualified the remarks by saying that their opinions were based on current trends.

Existing System: Dentists requiring portable equipment presently have to fabricate their own units. In the past, this has been done by Public Health dentists serving in Alaska and volunteer dentists delivering health care, under the sponsorship of over 50 nonprofit organizations,[4] in rural areas of developing nations. It is estimated that there are several hundred American dentists who offer such voluntary services during the summer, exclusive of W.H.O. dental programs. The problem investigator, Dr. Barry Simmons, from Athens, Georgia, founder of Dental Health International (funded

by the Agency for International Development), has spent the past 13 summers providing basic dental care to the rural poor in developing countries. Although the required specifications of equipment for use abroad will be slightly different than for American use, the work already done by Dr. Simmons in constructing the portable dental equipment and his experience in this area could be the basis for developing an advanced version.

The description of his equipment made up of commercially available components is given below:

The entire system is shown as it would be assembled in the field (Figure 1). For details, refer to the schematic diagram (Figure 2).

Although some of the individual components have been made portable as per the requirements laid down by individual dentists, the system as a whole leaves much to be optimized.

The heart of the system is a "dental unit" (4) called "Mission-Air" made by A-Dec, Oregon, one of the largest manufacturers of dental equipment. It was made to the specifications recommended by Dr. Simmons. This unit contains the control valving, pressure gauges, water coolant tank and assorted plumbing for attaching the various dental handpieces, oral suction, and a three-way syringe. This unit, weighing 16 KGS in the carrying case, is being sold by A-Dec at the rate of 3 to 5 per month.

The dental unit is powered by compressed air at 2.8-3.8 KG/CM^2, delivered by an AC motor or I.C. engine driven compressor (1) depending on field conditions. There is a holding tank (2) to cool the air down to reasonable temperatures (15^{o}-$21^{o}C$) and to relieve the compressor from having to run on a continuous basis. A vortex dryer (3) then dehumidifies the air before it enters the dental unit.

A lightweight dental chair (5) also made by A-Dec has an adjustable back support and legs for different reclining positions and heights.

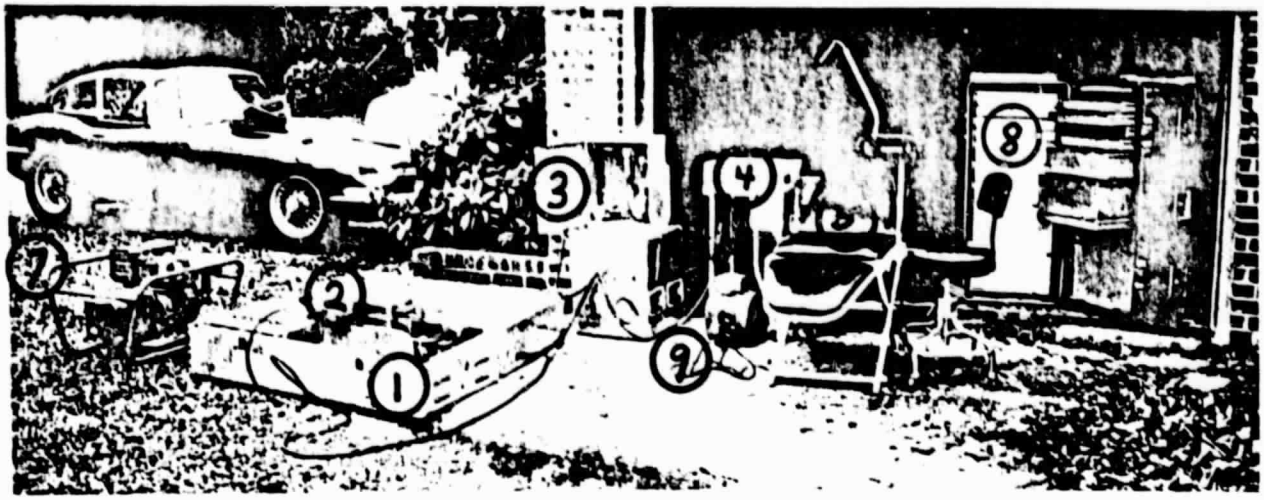


Figure 1

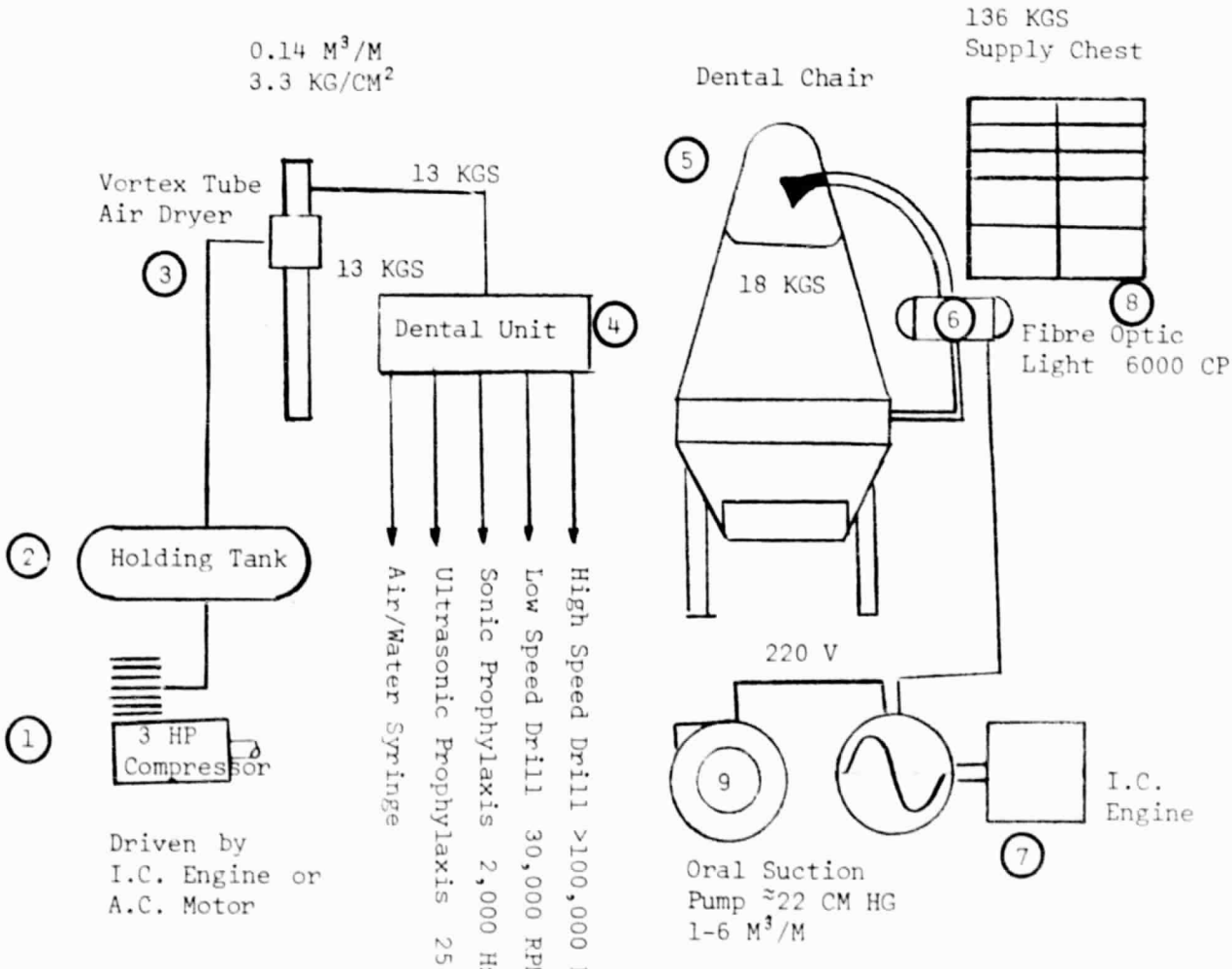


Figure 2

The chair has an approximately 6,000 candle power fiber optics light source (6) attached to it. The light source requires a 220-volt power supply (7).

Finally, there is a large folding cabinet (8) with all dental power tools, surgical equipment, and expendable items.

Specifications: Ideally, the system should be modular and lightweight for easy transport. The types of vehicles used to transport the equipment abroad vary from horse and camel backs to jeep-type vehicles and carved wood boats. Sturdy, well sealed, impact resistance containers are a must to protect equipment and supplies. Within the United States, modes of transport are light planes, helicopters, and automobiles. The equipment must be easy to set up in the field by technicians.

A. A compact and lightweight power source and compressor would make the existing system much lighter. The dentists need a high speed (100,000 rpm) and a low speed (30,000 rpm) handpiece with speed control, cooling water for drills, a three-way air-water syringe for rinsing, oral suction, and sonic and ultrasonic cleaning tools, all of which, at the present, are compressed-air driven. However, these need not be pneumatic if there are alternate ways of powering the tools.

B. A lightweight (9-13 KGS) dental chair, fully adjustable in height and reclining angle; should be, in addition, collapsible into a small volume.

C. An optimized inventory of surgical instruments and supplies should be packaged into a lightweight (13-18 KGS) supply chest. Currently, with the supplies, the unit weighs 130-180 KGS.

D. A compact sterilizing chamber (not shown) is required for the drills and instruments. Possibly, the unit could be built into the supply chest for a 2-in-1 function.

E. A dental X-Ray unit including a miniaturized processing lab also is highly desired by the dentists working in field locations. Locating the patient and the X-Ray head with no relative motion between the two is a problem in the field.

Actions Taken: Various NASA-developed technologies were identified throughout the course of the reporting period which have the potential of making significant contributions in four of the five problem areas described above.

A. Compressed Air Source. The BATeam contacted Dr. Robert Mallien from Milwaukee who also has developed compact and portable dental equipment for use in rural areas. In a joint effort with Dr. Mallien and a company in New Berlin, Wisconsin, called D&H Composites, a collapsible compressed air holding tank was developed using NASA and DOD-developed glass filament winding technology. A flexible resin developed by D&H Composites allowed the tank to be collapsed to 50% of original volume when not in service. (For details, see the preceding three quarterly reports--January-September 1977.) The weight of the tank is around 10 pounds which is a considerable improvement compared to the 25-30 pounds of a commercially available steel tank of the same volume. The composite tank was field tested in Colombia by the Marquette Medical Dental Team on the international project during the summer of 1977.

Pin hole type failures prevented the tank from being used effectively. Efforts are underway to further lighten the weight of the tank. Mr. Austin D. McHatton, an expert on engineering fabrics at NASA Langley Research Center, was consulted for possible use of synthetic fabrics in the tank design. He has proposed a cylindrical tank with a rubber bladder contained within a fabric sheath. The diameter will

be chosen to limit the hoop stress well within the yield stress limit for the fabric and the length of the cylinder will be adjusted for the given volume. Thus, after use, the tank could be rolled up much like a fire hose. The Good Year Company has been approached for the inner bladder design.

B. Dental Chair. A rotating litter chair used during the Skylab mission to test vestibular function (motion sickness) seems like a suitable design for a lightweight dental chair (see Figure 3). If made from the composite material support panels and aluminum tubing, the overall weight can be minimized. Furthermore, the various linkages could be disassembled into a compact transportation package. Dr. Jerry L. Homick, Johnson Space Center, is being consulted on the adaptation of this design for the dental application.

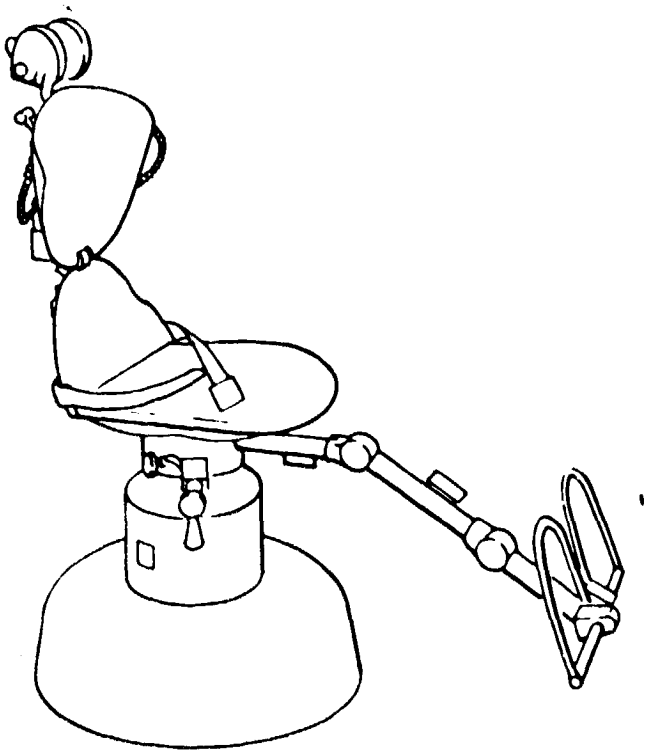
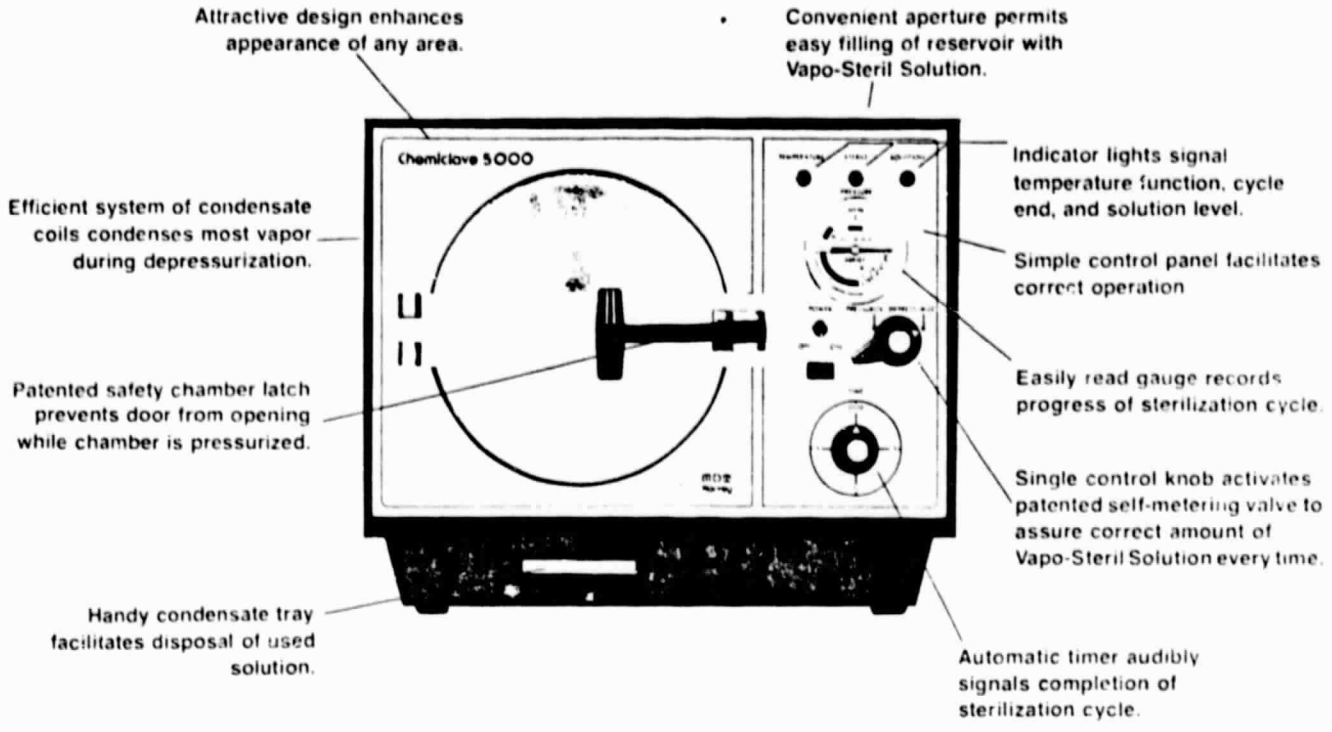


Figure 3. Rotating litter chair.

D. Compact Sterilizer. A commercially available chemical vapor sterilizer, made by MDT Corporation, El Segundo, California, the Chemiclave 5000 (Figure 4), weighs 18.18 KGS and operates at pressures in the 1.41-2.82 kg/cm^2 range. The BAT, in collaboration with Dr. Mallien and the MDT Corporation, is trying to develop a modified chemical vapor sterilizer. The weight reductions can be achieved without sacrificing structural integrity through the selection of composite materials to replace metallic components. Mr. Robert Baucom, composite materials expert at NASA Langley Research Center, has suggested the use of graphite reinforced poly-imides to construct the sterilizer pressure vessel. This composite has the capability to retain its original properties at the temperature (132°C) required in this process. Mr. Baucom indicated that the first few prototype vessels could be fabricated at Langley if planned and scheduled through the proper channels. These activities will be coordinated through Mr. John Samos, TU Officer.

The MDT Corporation has provided a Chemiclave 5000 sterilizer and all the blueprints necessary to carry out necessary modifications. If the prototype pressure vessel proves successful, more comprehensive modifications will be undertaken. Dr. Robert Runnels, Chairman of the MDT Corporation, has shown great interest in this project. Dr. Runnels has indicated that if the NASA solutions seem practical, his company would then be willing to consider co-funding of further development of the lightweight sterilizer.

E. Portable Dental X-Ray Unit. The most significant NASA technology contribution perhaps will result in this area. The hand-held dental fluoroscopy unit, developed at Goddard Space Center, called the LIXI-scope (Low Intensity X-Ray Imaging Scope), seems to be an ideal remedy to the problem of field x-ray work. In rural areas, hard-copy x-rays



Technical Data:

Overall Dimensions	13" (33.02 cm) wide x 10½" (26.67 cm) high x 19½" (49.53 cm) deep
Chamber Dimensions	6" (15.24 cm) diameter x 11" (27.94 cm) deep
Reservoir Capacity	19 fluid oz. (.58 litre)
Power Supply	120V/A.C., 60 Hz, 500 Watts
Current	4.2 Amps
Operating Pressure	20 - 40 psi (1.41 - 2.82 kg/cm²)
Operating Temperature	270°F ± 5° (132°C ± 2°)
Weight	40 pounds (18.18 kg)
Shipping Weight	49 pounds (22.27 kg)

Figure 4. The Chemiclave 5000

are not necessary if a screening capability exists. The BAT will take a leading role in the commercialization of the LIXIscope. This will be discussed in a separate section of the report, entitled "Commercialization Activities."

Persons Contacted During Telephone Survey:

Dr. Everett Clauss, Exec. Director, Christian Dental Society, Littleton, CO.
Dr. Lloyd Cloud, Asst. Chief for Program Operation, Indian Health Service, Albuquerque, NM.
Dr. Joseph Doherty, Dental Director, Wisconsin Public Health.
Dr. George Gellespee, Chief of Dental Section, Pan American Health Organization, Washington, DC.
Dr. Charles Goldstein, University of Southern California School of Dentistry.
Dr. John Green, Chief Dental Officer, Office of Asst. Sec. for Health, HEW, Public Health Service, Washington, DC.
Col. Ed Larr, U.S. Army Dental Corps.
Mr. Joe Leiser, Columbus Dental Co., Columbus, OH.
Dr. McCarten, Chief Dentist, Indian Health Service.
Dr. Charles Meyer, Community Dentistry Dept., Creighton University, Omaha, NB.
Dr. Tom Pickles, Dental Director, Oregon Public Health.
Dr. Robert Runnels, Chairman, MDT Corp., El Segundo, CA.
Dr. Carlos Saldana, Brooke Army Medical Center, San Antonio, TX.
Mr. Phil Smith, Customer Service Manager, A-Dec, Newberg, OR.

Bibliography

1. Robert L. Nolan, Jerome L. Schwartz, "Rural and Appalachian Health," Publisher--Charles C. Thomas, 1973.

2. Wesley O. Young, David F. Striffler, "The Dentist, His Practice, and His Community," W.B. Saunders Co., 1964.

3. James Morse Dunning, "Principles of Dental Public Health," Harvard University Press, 1962.

4. "Demand Abroad for Dental Personnel and Material Directory of Programs," Council on International Relations, American Dental Association, 1972.

5. Tomm H. Pickles, Paper presented at Title V Workshop, Las Vegas, November 10, 1976.

Problem Investigator: Dr. Barry Simmons, Dental Health International, Athens, Georgia; and Dr. Robert Mallien, American Red Cross, Milwaukee, WI.

BATeam Coordinator: Bakki Kudva.

Problem UW-37 - Primary Care Education and Response

Help Wanted: Identification of best applications, publisher interest.

Abstract: Training of both intermediate-level health care providers and of patients to meet primary care needs can be greatly advanced with a NASA development, the IMSS Checklist.

The Need: Now more so than ever before, a need exists for the clear, organized, and efficient transfer of information. This is true in all fields as data and knowledge increases, but it is nowhere more true than in medicine. Vast sums of money are now spent for health care; the field is constantly broadening, becoming more complex and growing increasingly intertwined with other aspects of modern life.

One aspect of the evolution taking place in modern medical practice is the renewed emphasis upon primary care. Once the most familiar form of medicine, it had gradually become replaced with specialization and highly technical approaches to the delivery of health care. The pendulum has clearly begun to swing back as new forms of primary care are evolving in this country. Among these are new provider types, who extend the doctors' capabilities--the Physicians Assistants and Nurse Practitioners--and a growing reliance upon the patient as an important partner in medical care.

As the delivery of health care becomes more complex and diversified, so too does the need grow for better instruments of communication. The new participants in the health care process, the intermediate-level extenders and the patients, both need good training aids to develop and secure their effectiveness.

NASA Technology: One of the problems faced by physicians charged with safeguarding the health of astronauts was the problem of health care in the space-bound capsule. It could not be expected that a physician would be on board for every mission, so it was clear that astronauts must be trained and provided with the capability of attending to their own medical needs.

The solution to this problem for Skylab was to develop a checklist, to be used with on-board diagnostic and therapeutic materials for medical purposes. This development, unique to the space program, is known as the IMSS Checklist. By means of these materials, individuals without extensive medical training were prepared to meet medical emergencies in the most effective and expeditious manner. The Checklist has already been adapted by a NASA field center for application to emergency medical care on earth, but other applications seem even more promising.

Actions Taken: Plans for the transfer of this technology have progressed to the point that a BAT-sponsored project has been initiated. The purpose of the project is to (1) investigate in more depth the possible applications for the NASA checklist, (2) prepare outlines and sample adaptations of the checklist for the most promising applications, and (3) develop a commercialization package and strategy for securing the commitment of a publishing company to finish the work and make the results widely available.

At the outset of the project, the following applications were under consideration:

1. Training aid for family physicians teaching clinical problem-solving to medical students and residents.

2. Training aid for faculty teaching medical decision-making to physician extender trainees, e.g., Physicians Assistants, Nurse Practitioners, Pharmacy Practitioners, etc.
3. Reference manual for use by those in #2 (useful in industrial medicine, remote site practice settings, etc.).
4. Medical guide for hunters, fishermen, backpackers, boaters with limited or delayed access to physician care.
5. Medical guide for military and public safety personnel required to give emergency care in remote areas (Coast Guard, state police, etc.).

These plans have been discussed with Dr. Paul Buchanan, Director of the Biomedical Office at the NASA/Kennedy Space Center, who played a major role in the development of the NASA Checklist. He has agreed to collaborate with us on the project. Moreover, he believes that the objectives under consideration in this project are the early targets for new ways in which medical care will be delivered in the future. He is interested in such new tools both for widespread public use as well as to satisfy some upcoming NASA needs to provide effective, remote medical care.

Problem Investigator: Dr. John E. Renner, Chairman, Dept. of Family Medicine and Practice, University of Wisconsin-Madison.

BATeam Coordinator: William N. Fetzner.

Problem UW-39 - Pupillometer--A Device to Continuously Measure Pupil Diameter

Help Wanted: NASA technology in solid state detectors and fiber optics.

Abstract: There is a need for an inexpensive device to accurately measure the pupil diameter in real time. Some of the important and useful applications of such an instrument are in clinical neurologic diagnosis, monitoring during anesthesia, behavioral screening, pharmacodynamic research, and assessment of narcotic dependency.

The Need: Experimental and clinical studies of the pupil in the fields of physiology and pharmacology have drawn much attention during the past century. However, a method of quantitatively measuring pupil response to various stimuli, named "Pupillography" by the late Dr. Otto Lowenstein, was introduced only 50 years ago. Ever since, many Pupillographic methods such as direct measurement using lenses and scales, photographic methods and infrared scanning methods have been tried.

The constrictor sphincter muscles of the pupil derive their excitory impulses from the parasympathetic neuro-system. The light-reflex feedback pathway is included in this system, where impulses originating in the retina are fed back through a two-nerve relay system to the pupil. The sympathetic nervous system, on the other hand, innervates the dilator muscles of the pupil through a variety of pathways. In addition to having inhibitory effects on the parasympathetic relay system, the sympathetic pathways can directly act on the dilator muscles through the sympathetic outflow from the spinal cord at the cervical and thoracic levels. Both systems are influenced by centers in the upper brain (cortex).[1]

The involvement of the pupil in these systems makes it an excellent indicator of lesions and disorders of the system when considered along

with other symptoms and a thorough understanding of the complex interconnections.

The effects of clinical lesions on pupil response have been well documented. Figure 1 shows pupillograms corresponding to the clinical lesions most often encountered in practice (for details, see reference 1).

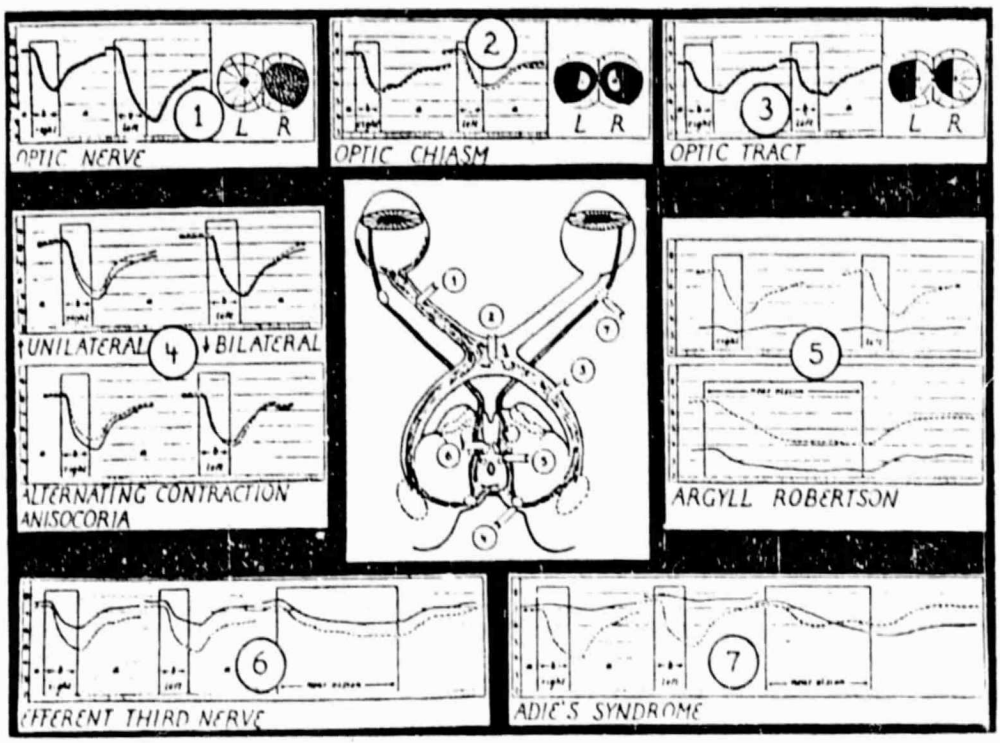


Figure 1. Clinical lesions in the parasympathetic reflex arc. Y-axis of pupillogram shows pupil diameter in mm and x-axis the time. The numbers 1-7 indicate the lesions most often encountered in practice. The corresponding pupillograms 1-7 show changes in pupillary reactions caused by these lesions.

Due to the higher brain center links with the pupillary system, psychotic disorders, drug addiction, alcoholism, etc., have been shown to cause changes in the pupil response. Experiments conducted in Viet Nam have shown pupil diameter to be an excellent differential indicator of heroin intoxication and withdrawal.[3] Pupil response in Schizophrenics has been documented by Rubin.[4]

During the induction or anesthesia, the patient may be in an excited state and his pupils are often dilated. As anesthesia deepens, upper brain inhibitory influences on the parasympathetic relay system are cut off, resulting in constricted pupils. But if anesthesia becomes dangerously deep and begins to encroach upon the mid-brain, the pupils dilate again and fail to react to light due to inactivation of the light reflex system.[1] This means that monitoring pupil response during surgery could be a valuable input in controlling the state of anesthesia.

Specifications: In the past, several systems have been described and tried. Infrared scanning techniques are described by Lowenstein[2] and Troelstra.[5] In both cases, the I.R. radiation passes through scanning holes in a rotating disc or drum and illuminates the eye. Reflected radiation from the eyeball is collected by a photomultiplier tube, the output of which goes through the electronics that extract the pupillary diameter from the signal.

Other techniques using infrared film and motion picture photography have been described by Lowenfeld.[6] Infrared radiation is used in most cases due to the insensitivity of the retina to it.

The state of the art now is to use silicon vidicons to scan the image formed by I.R. optics. The vidicon output is fed into computers through a video-digital interface. Depending on hardware and software capabilities, the pupil diameter can be calculated in addition to tracking the eye and focusing the image.[7,8] One of these schemes is shown in Figure 2. Devices that can track the eye are called Oculometers.

One of the reasons deterring the widespread use of pupillography as a common diagnostic tool is its cost. Commercially available systems start at $10,000 (Applied Science Lab, Waltham, Massachusetts) and go as high as $100,000 (Honeywell). Thus, it is desirable to have an inexpensive, compact,

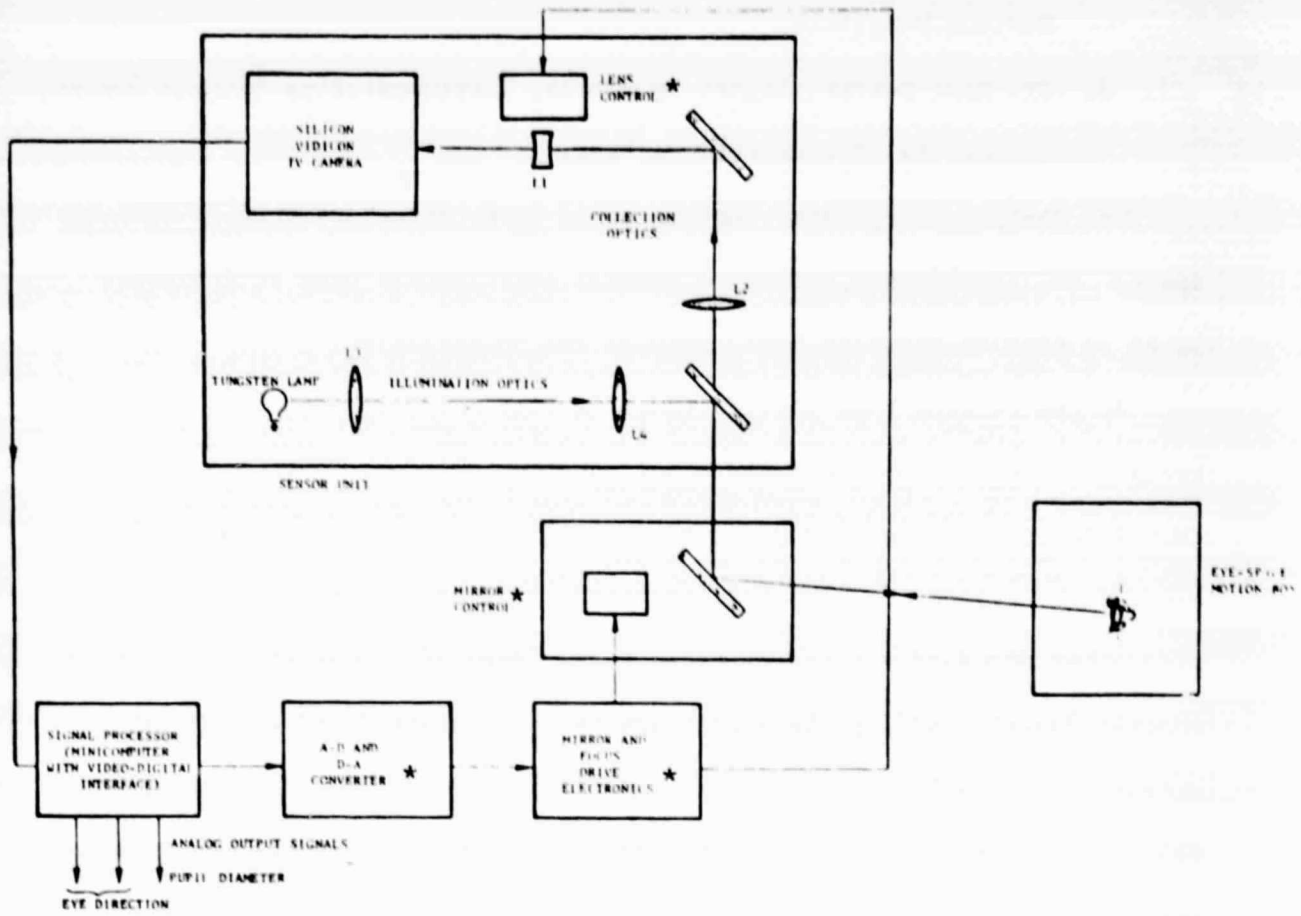


Figure 2. Schematic of the cubic-foot remote oculometer. (*These items deleted in cubic-inch version.)

accurate (±0.5%) and linear (99%) pupillometer that can be routinely used by medical personnel without requiring the continuing services of a technician or an engineer. Pupillograms as shown in Figure 1 can be saved to reflect the history of pupillary response.

Actions Taken: A new design for a pupillometer was proposed by the BATeam coordinator. The design is being shown to several professional persons with varied backgrounds for a technical evaluation. The design, which involves a contact lens-fiber optic system was shown to the following persons.

1. Dr. J. H. Trainor, Specialist in Solid State Detectors at Goddard Space Flight Center.

2. Dr. Ben Rusy, Professor, Anesthesiology, University of Wisconsin-Madison Hospitals.
3. Mr. Gene Nutter, Expert in Optics, Instrumentation Systems Center, University of Wisconsin-Madison.

The design incorporates certain solid state detectors used by NASA in space. Dr. Trainor has agreed to provide consultation time at a minimal level in view of his very heavy mission responsibilities.

At the current time applications for such a device seem to be only in research studies. Dr. Rusy and other anesthesiologists contacted felt that such a device would not be necessary to monitor the state of anesthesia in view of the reliability and predictability of modern anesthetic agents and also other standard monitoring techniques. However, other applications in pharmacodynamics and ophthalmology are being considered and appropriate persons in those fields are being contacted. The market potential of the design is being evaluated. The design will be reported to Mr. Don Friedman, Contract Monitor at GSFC as it becomes finalized.

References:

1. Walsh, F. B., Hoyt, W. F., "Clinical Neuro-Ophthalmology," Vol. 1, 34rd Edition, Williams & Wilkins Co., 1969.
2. Lowenstein, Otto, Lowenfeld, Irene, "Electronic Pupillography--A New Instrument and Some Clinical Applications," A.M.A. Archives of Ophthalmology, Vol. 59, p. 352, March 1958.
3. Robinson, Malcolm G., et al., "Assessment of Pupil Size During Acute Heroin Withdrawal in Viet Nam," Neurology, Vol. 24, p. 729-732, August 1974.

4. Rubin, L. S., Barry, T. L., "Amplitude of Pupillary Contraction as a Function of Intensity of Illumination in Schizophrenia." Biological Psychiatry, Vol. 11, No. 3, p. 267, 1976.

5. Troelstra, A., et al., "A Digital Pupillometer," Medical Research Engr., Third Quarter, p. 11, 1966.

6. Lowenfeld, I. E., Rossbrother, H. D., "Infrared Pupil Camera," American Journal of Opthalmology, Vol. 78, No. 2, p. 304, August 1974.

7. Merchant, John, et al., "Remote Measurement of Eye Direction Allowing Subject Motion over one Cubic Foot of Space," IEEE Transactions on Biomedical Engineering, Vol. BME-21, No. 4, July 1974.

8. Merchant, John, "Fixation Point Measurement by the Occulometer Technique," Optical Engineering, Vol. 13, No. 4, p. 339, July 1974.

Problem Originators: Mr. Rodney B. Murray and Dr. Ronald J. Tallarida, Dept. of Pharmacology, Temple University, Philadelphia, Pennsylvania.

BATeam Coordinator: Bakki V. Kudva.

Problem UW-41 - Design Improvements for Neonatal Intensive Care Incubators

Help Wanted: NASA technology in aerodynamics and environmental control.

Abstract: There is a need for improvements in infant incubator design to achieve a stable internal environment unaffected by medical procedures requiring access to the infant. Aerodynamic techniques might help to regulate air flow patterns.

The Need: It has been long known that survival rates of premature infants can be raised by reducing their heat loss.[1,2] Heat production depends largely upon biological oxidation and is a result of the metabolic activity of all the cells of the body at rest, together with the additional production due to muscular activity. When a thermal gradient exists, metabolic activity rises above basal as much as by 120-140% at 28°C ambient, in a full-term infant as opposed to 0-25% rise in an adult at the same temperature.[2] An infant lacks the fat and the subcutaneous tissue layer relative to the adult and in addition has a higher surface area to body weight ratio. Thus, heat generated in the core of the infant's body conducts with ease to the surface from which it is then dissipated at a much higher rate than in adults.

To maximize the chances for survival of a premature or sick infant, an "optimal environment" has to be created in which the infant not only has a normal body temperature (32-36°C) but also is not stressed metabolically by a stimulating skin-environment thermal gradient.

Heat gains or losses can be radiant, convective, conductive, and evaporative. All these factors have to be accurately controlled to keep the infant's body temperature relatively constant.

Currently available incubators attempt to prevent these losses by convectively heating the air within. Humidity levels are maintained between 50-60% R.H. Though heat loss through evaporation is minimal due to lack of sweating in premature infants,[2] humidity must be maintained at sufficiently high levels to prevent irritation of mucous membranes and to decrease the viscosity of secretions in the pulmonary airways. The incubator heaters are servo-controlled with temperature feedback either from the baby's skin or from the return air duct. The temperature us either controlled by means of a simple ON-OFF operation of the heater or by a proportional heat control technique where the rate of heating is proportional to the difference between the desired skin temperature and its actual value. Behavior of these two systems in time is shown in the temperature versus time graph in Figure 1.

Environmental temperature variations as large as 5°C can be seen and in some cases exceed the skin temperature of the infant (Figure 1-a and 1-b). In addition, due to air flow patterns and velocity profiles, there are thermal gradients within the hood itself. Such transitions can stimulate apneic and bradycardiac spells in sensitive infants.[3,4] A more desirable environment that is "metabolically soothing" to newborns is one where the temperature of the air is constrained to 2°C below that of the infant's skin temperature (Figure 1-c).

The problem investigator, Dr. Perlstein, has done extensive work in this area. To achieve the environment described above, he used a computer (PDP 11/20) to monitor skin temperature, air temperature, incubator wall temperatures, heart rate, and respiratory rates of the infant and control heating and incubator operation. An algorithm programmed into the computer is the key to the maintenance of such an atmosphere. Chance of survival of infants with RDS under computer care was proven to be significantly higher than those cared for routinely.[5]

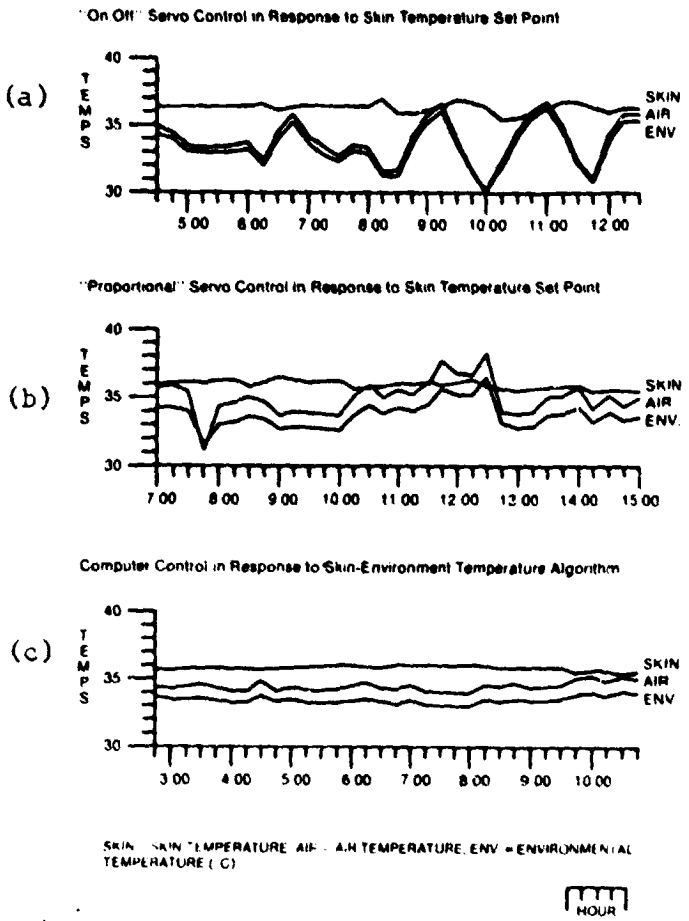


Figure 1. Eight-hour summaries of temperature recorded in isolette incubator chambers heated using three different control techniques.

In present-day incubators there are some additional problems that need rectification. When a skin-referenced probe becomes covered by a sterile towel, a diaper, a flailing arm of the baby or is sandwiched between the baby and the mattress, the heating of the probe causes the heater to be turned off exposing the baby to a cold stress. Or when the thermistor is wet due to milk, urine, or other solutions, it will sense its own evaporative loss, causing an inappropriate response.[6]

* From Perlstein, P.H., "Thermal Control" in Iatrogenic Problems in Neonatal Intensive Care, Report of 69th Ross Conf. on Pediatric Research, p. 75, Feb. 1976.

The premature or the sick infant requires more attention and care than the healthy one. Constant opening of ports for access to the baby, lifting of the head for procedures like x-ray, blood sampling, catheterization, etc., cause the incubator temperature to drop by substantial amounts (up to $8^{o}C$) to room temperature. Thermal inertia of the hood volume, incubator heating circuit and the response time of the thermistor introduce delays in the reheating-to-equilibrium time. This, unfortunately, is more harmful to the sick or premature infant than to a healthy full-term baby.

Specifications: An improved incubator design should incorporate measures to overcome the shortcomings in the present incubators on the market.

Air flow patterns and temperature profiles within the incubator hood have not been modeled, measured, or documented. Turbulent zones in the vicinity of the access ports or turbulence caused by lifting of the hood or insertion of hands through ports will draw room temperature air into the hood causing the temperature transitions. The aerodynamics technology and expertise of NASA should help in modeling and designing optimal air flow patterns. Air flow within should be designed such that even with ports open or hood lifted, the baby should be constantly bathed in conditioned air at a positive pressure.

Temperature measurement techniques in flowing air and relative humidity sensors would be used in the design process. Spacecraft, spacesuit environmental control systems design technology seems to be applicable.

To minimize heat loss due to conduction, the mattress could be designed with a material such as "Temper Foam," which not only would distribute the baby's weight evenly but also, because of its semi-open cell structure, permit passage of preconditioned air through it.

Actions Taken: The BATeam coordinator met with Dr. Dan Bencze, Aeronautical Engineer of NASA Ames Research Center, during a recent visit to Moffett Field. In the meeting, it was agreed upon that the first step would be to determine if the problem could be solved using rather straightforward aerodynamic engineering principles or whether advanced NASA flow and temperature field computational techniques are necessary. In the former case, NASA involvement is not warranted. Dr. Bencze has agreed to arrange a one-day workshop at Ames Research Center to discuss this problem if the problem originator and R&D engineers from any interested companies are willing to travel to Moffett Field. The BATeam coordinator will attempt to organize the trip in the near future.

Bibliography

1. Silverman, W. A. et al, "Influence of the Thermal Environment Upon the Survival of Newly Born Premature Infants," Pediatrics, Vol. 22, p. 876, 1958.
2. Buetow, K. C. et al, "Effect of Maintenance of 'Normal' Skin Temperature on Survival of Infants of Low Birth Weight," Pediatrics, Vol. 34, p. 163, 1963.
3. Perlstein, P. H. et al, "Apnea in Premature Infants and Incubator Air Temperature Changes," New Eng. J. Med., 282, p. 461, 1970.
4. Perlstein, P. H. et al, "An Environmental Trigger to Cardiac Instability in the Neonate," Amer. Ped. Soc. Meet. Abs., Atlantic City, May 1972.
5. Perlstein, P.H. et al, "Computer-Assisted Newborn Intensive Care," Pediatrics, Vol. 57, p. 494, 1976.
6. Edwards, N., "Radiant Warmers," in Iatrogenic Problems in Neonatal Intensive Care, Report of 69th Ross Conf. on Pediatric Research, Feb. 1976.

Problem Originator: Paul H. Perlstein, M.D., Newborn Division of Department of Pediatrics, University of Cincinnati, Cincinnati, Ohio.

BATeam Coordinator: Bakki V. Kudva.

Problem UW-42 - Diagnostic Radiographic Image Storage System

Help Wanted: Verification of NASA technology; more applicable NASA technology; commercialization possibilities.

Abstract: Present techniques for storage and retrieval of patient x-ray films are cumbersome and time-consuming. New techniques are needed to improve x-ray department efficiency and to reduce the incidence of error in the filing of patient films.

The Need: The vast majority of hospital patients have at least one x-ray taken during a hospital stay. Many patients have numerous exposures taken during a series of hospital admissions. The physical volume of the films which must be stored (for both medical and legal reasons) for several years is very large. Large hospitals may employ several persons who do nothing but retrieve past patient films for comparison with a current radiologic examination. In addition to the problem of providing convenient storage space for a large volume of films, there is difficulty in maintaining an accurate film file index. An index is required to indicate if and when a patient underwent a previous radiographic examination. Manual index systems are prone to misfiling errors especially during emergencies and late night examinations. Files may be overlooked or misplaced and redundant files may be created. Needed is a system for storage and retrieval of radiographic images which occupies a smaller physical space and which includes an integrated file index.

Specifications: A significant reduction in present film size would be desirable. Equipment size may not be critical if remote image input and display is provided, however. Current commercially available microfilm

techniques do not in general provide sufficient resolution. The required resolution is dependent upon the procedure and the x-ray tube focal spot size. A common tube with a nominal focal spot size of 2 mm can typically resolve a pair of lines 1 mm apart. A high resolution .5 mm nominal focal spot size tube may allow resolution of .25 mm line separation. Required film format may also change with procedure.

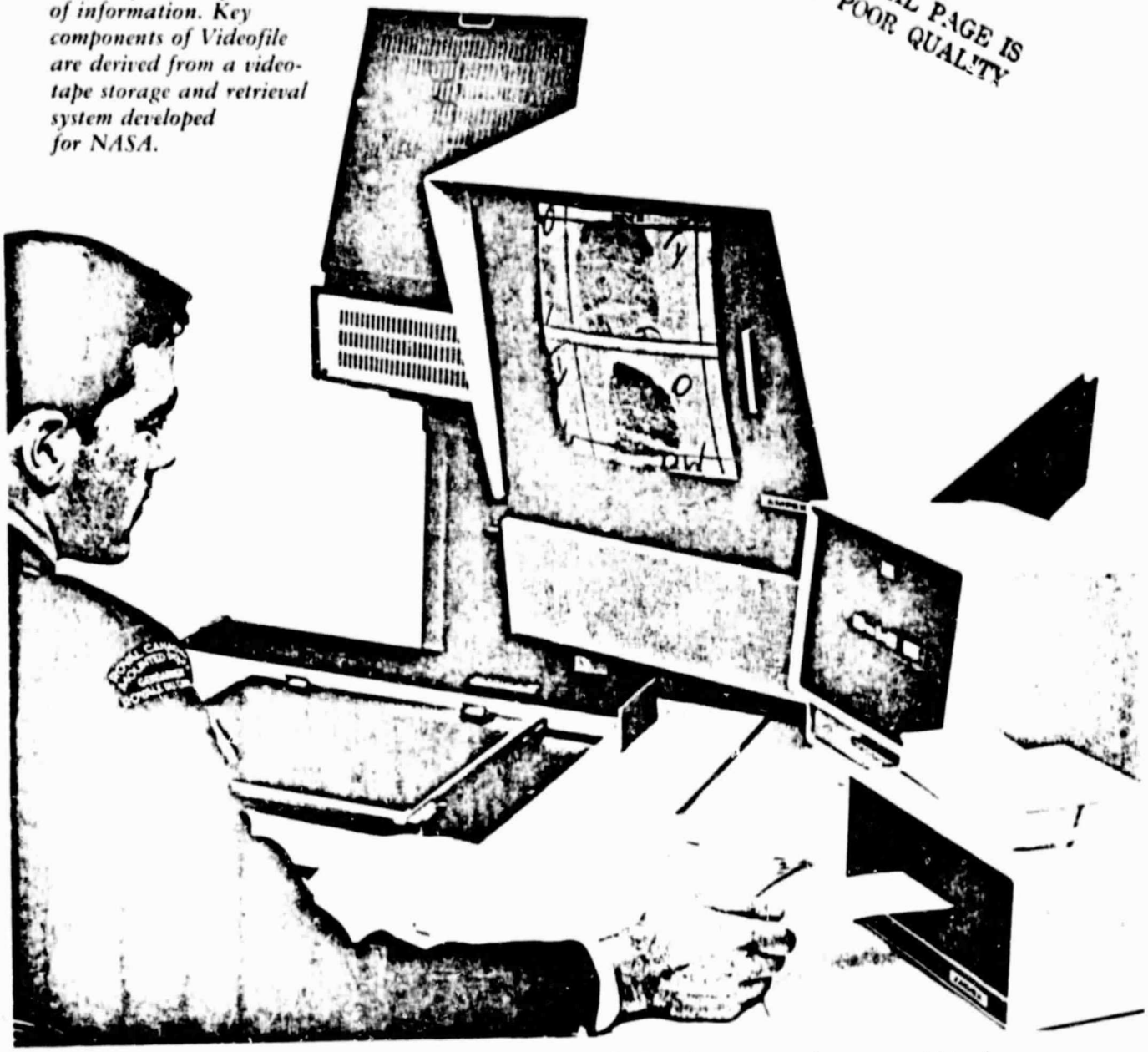
Detailed specifications for an improved system which would be suitable for the majority of x-ray procedures are being prepared. A possible system might utilize fluoroscopic and video processing techniques to directly digitize the x-ray image without the use of expensive film. Bandwidth compression video coding schemes developed at Goddard Space Center may be used to reduce the data storage requirements. Gray scale manipulation may also be desirable prior to data storage. Digitized images may be magnetically recorded on tape or discs or some other permanent medium. Digitally stored images would also allow an integrated patient index system which would reduce errors in record retrieval.

Action Taken: A search for applicable NASA technology is underway. A system developed for NASA-Marshall by Ampex Corp. (see Figure 1) may be amenable to modification for this use.

Problem Investigator: Mr. Fred Glab, Radiology Department Manager, Methodist Hospital, Madison, Wisconsin.

BATeam Coordinator: Everis R. Engstrom.

Videofile is used by a number of law enforcement agencies in the U.S. and Canada. It is a computerized pictorial record-keeping system offering high reliability and rapid retrieval of information. Key components of Videofile are derived from a videotape storage and retrieval system developed for NASA.



Videofile for Law Enforcement

Components of a videotape storage and retrieval system originally developed for NASA have been adapted as a tool for law enforcement agencies.

Ampex Corp., Redwood City, Cal., built a unique system for NASA-Marshall. The first application of professional broadcast technology to computerized record-keeping, it incorporates new equipment for transporting tapes within the system. After completing the NASA system, Ampex continued development, primarily to improve image resolution.

The resulting advanced system, known as the Ampex Videofile, offers advantages over microfilm for filing, storing, retrieving, and distributing large volumes of information. The system's computer stores information in digital code rather than in pictorial form. While microfilm allows visual storage of whole documents, it requires a step before usage —developing the film. With Videofile, the actual document is recorded, complete with photos and graphic material, and a picture of the document is available instantly.

Figure 1

Problem UW-43 - Intracranial Pressure Display/Alarm System

Help Wanted: Evaluate NASA technology; other NASA technology; commercialization possibilities.

Abstract: Intracranial pressure monitoring is becoming a common clinical practice in neurosurgical intensive care units. There is a need for a system to conveniently display long periods of intracranial pressure data and to announce clinically important changes with an appropriate alarm.

The Need: Intracranial pressure (ICP) monitoring aids in the proper administration of drugs and surgical therapy for cerebral edema and in the diagnosis of various conditions such as head trauma, edema and recurrent mass lesions, multi-system diseases such as Reye's Syndrome, and adult onset hydrocephalus. Currently, patients in neurosurgical intensive care can be monitored for ICP for periods up to 30 days pre- and post-operatively. Typically, the ICP waveforms are recorded on a paper strip chart recorder. This format is inconvenient for viewing by nurses and physicians who may be in several different places in a multi-bed unit and a great deal of paper is accumulated which may contain unnecessarily recorded information. What is needed is a system which continuously displays up to three hours of ICP data on a high resolution cathode ray tube and which automatically sounds an alarm and makes a permanent recording of ICP upon recognition of particular types of waveforms. Two types of ICP waveforms are defined in Figure 1. In addition to these patterns, it would be desirable to automatically recognize when the ICP quickly exceeds set limits or when the baseline pressure slowly changes by more than a particular limit.

Systems which perform similar types of display/alarm functions for electrocardiographic signals are now commercially available. In general,

DEFINITIONS OF TERMS

Recorded changes in intracranial pressure may occur in the form of characteristic patterns or waves. Two distinct types of waves have been described by Lundberg:[1]

A-waves. Ominous episodic elevations of ICP to values of 50-100 mmHg (67.5-135 cmH_2O) 5 to 20 minutes in duration, usually superimposed on an already elevated baseline ICP. Also known as plateau waves. See example below.

B-waves. Short-term oscillations lower in amplitude than A-waves occurring at a rate of 1/2 to 2 fluctuations per minute. Clinically less significant than A-waves, but B-waves occurring in runs in which the waves exhibit regularity in shape, amplitude or rate tend to be associated with pathological depression of consciousness and according to our findings, often precede the appearance of an A-wave.

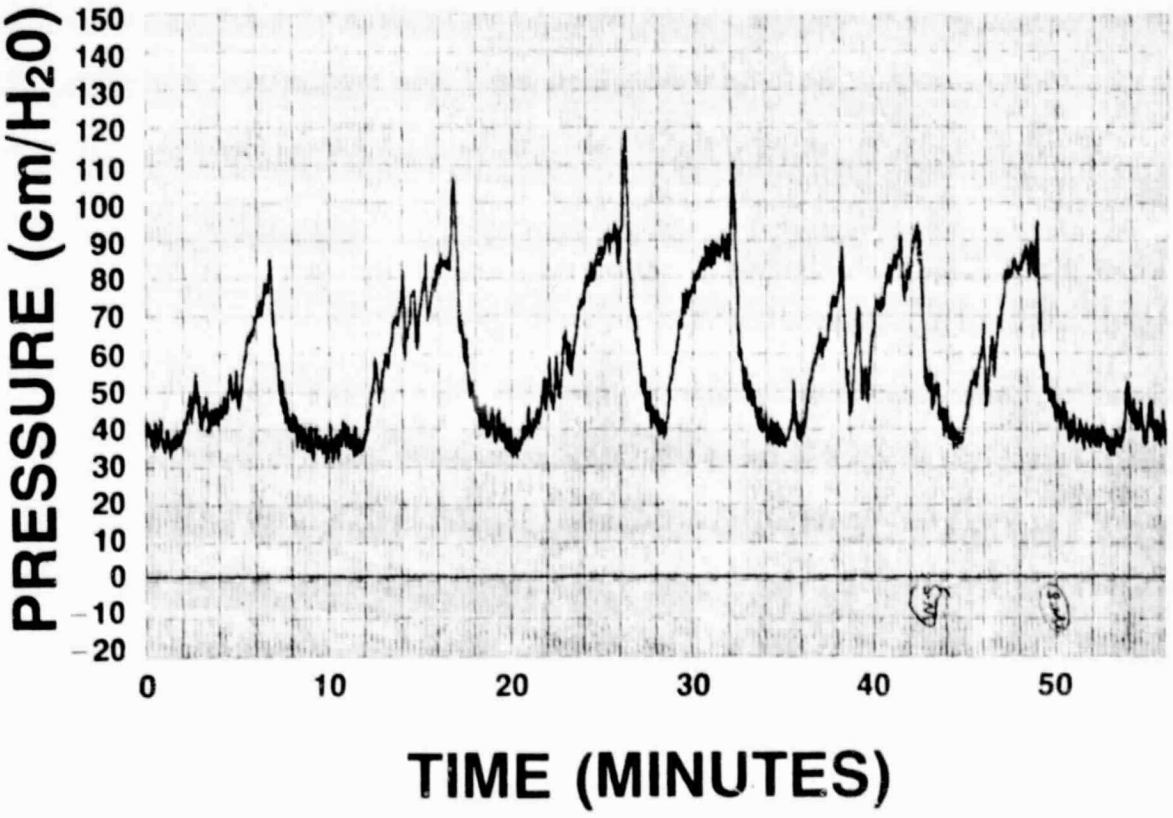


Figure 1. Typical A-waves recorded with the fiber optic ICP monitoring system. From: "The use of a fiber-optic intracranial pressure transducer in clinical practice," by A.B. Levin and L. Frazin. Presented as a Scientific Exhibit at the Annual Meeting of the American Association of Neurological Surgeons, San Francisco, April 1976.

[1] Lundberg, N. "Continuous recording and control of ventricular fluid pressure in neurosurgical practice, Acta Psychiat. & Neurol. Scand. (Suppl. 149) 36:1-193, 1960.

these systems cannot be readily converted to the display of ICP waveforms as they are designed for the short-term display of much higher frequency waveforms. For commercially available displays, about 1,000 samples or less are taken during the brief interval displayed on the screen. If a display period of three hours could be achieved, then for 1,000 samples, the resulting band width would be approximately DC-.05 Hz (3 cycles per minute). This frequency limit is high enough to preserve the type B waves (Figure 1) that have been observed in ICP data.

Specifications: The display format should be flexible to allow for the unique requirements of different institutions. The most common configuration would provide for a central CRT monitor which displays approximately three hours of ICP waveforms from each of four patients. Remote displays at the bedside may be desirable. Each display channel should be calibrated for a pressure range of 0-200 cm H_2O with a bandwidth of DC-2 cycles per minute or more. Patterns should be recognizable from a distance of 20 feet or more. The system should be able to display types A and B waves as well as maximum, minimum, and baseline pressure changes exceeding setable limits. Upon recognition of one of these conditions, both visual and audible alarms should be activated. Additionally, a permanent copy of the displayed information should be initiated and continued until the alarm condition is reset.

Actions Taken: A search for applicable NASA technology has been initiated. A biomedical monitoring and display system developed for JSC may be applicable.

Problem Originator: Dr. Allan B. Levin, Division of Neurological Surgery, University of Wisconsin Hospitals, Madison, Wisconsin.

BATeam Coordinator: Everis R. Engstrom.

Problem UW-45 - Sorbents for Detoxification of Uremic Patients

Help Wanted: Verification of NASA technology; more applicable NASA technology; commercialization possibilities.

Abstract: An entirely new concept of detoxifying patients with chronic renal failure, through selective adsorption of uremic toxins with special sorbents, is gaining popularity on the clinical scene. However, there is a need for effective urea removal. The NASA technology of recovering potable water from urine by the breakdown of urea in a biologic fuel cell might be applicable here.

The Need: Passage of public law PL-92-603 as an amendment to the Social Security Act provided financial assistance to patients with irreversible kidney failure. The act has extended treatment to a patient population estimated at 30,000 in 1976.[1] Dialysis is an expensive treatment. The annual cost of dialysis was $14,000 in a hospital and $5,000 in the patient's home in 1968.[2] By conservative estimates then, the annual expenditure on dialysis in the United States alone is around $300 million.

In the past decade, considerable improvements have been made in the design and development of membrane dialyzers. The principle of operation of a membrane dialyzer lies in the osmotic gradient caused across the semipermeable membrane which drives the mass transport of various solutes from the blood, flowing on one side of the membrane, to a dialysate on the other. Dialysis suffers from various shortcomings, some of which, besides the high cost, are: bulky equipment, need to immobilize the patient, need for a toilet drain or a kitchen sink, infection at the point of entry/exit in the patient's circulatory system.

Detoxification of uremic patients through selective adsorption of uremic toxins with special sorbents (a compound capable of selectively binding the toxin) is an entirely new concept, developed in recent years, which would hopefully overcome the disadvantages of dialysis. There are two possibilities for the use of sorbents.

(1) Introduction of selective sorbents into the dialysate bath of the artificial kidneys causes uremic toxins to be irreversibly bound as they cross the membrane. This maintains a constant, high concentration gradient for the transport of the toxins, thus requiring very small volumes of dialysate which can be continuously regenerated with the aid of sorbents.

(2) Selective sorbents for urea and other toxins can be directly fed into the GI tract allowing the transport processes to occur across the surface of the intestinal mucosa (see Fig. 1).[5] The sorbents then, with the bound toxins, would be rejected along with the feces. This has the great advantage of not requiring a connection with the patient's circulatory system. Once selective sorbents have been perfected, a slurry made up of the dialysate solution and the sorbents can be allowed to stay in an isolated loop of the small intestine (a technique developed by Schloerb[3] and Clark[4] for dialysis treatment using large quantities of dialysate) over a period of time before replacement.

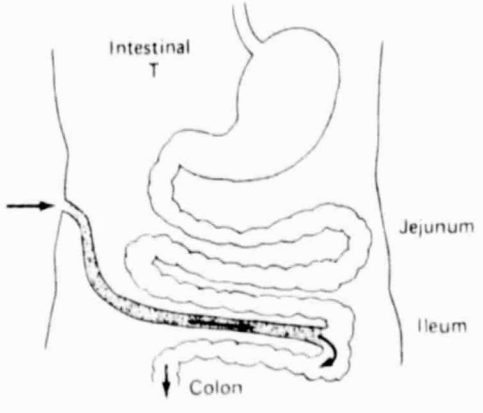


Fig. 1. *One-half of the jejunum and one-half of the ileum can be formed in a T-loop which then becomes available for dialysis adsorption and perhaps production of amino acids.*

Another approach in the use of sorbents in the GI tract is to microencapsulate the different sorbents in a polymeric material such as cellulose acetate butyrate. The microcapsules containing stabilized urease, charcoal, ethylene-maleic acid, and various ion exchange resins can then be administered orally. The electrolyte balance then would be maintained by selective adsorption taking place in the gut. Experiments done on animals by Gardner[6] and Sparks[6] show promise in the effectiveness of this technique. Thus, use of sorbents in uremia can greatly reduce costs and the tediousness of today's dialysis procedures.

Molecules such as creatinine, uric acid, etc., can be removed by using charcoal. Similarly, phosphates, potassium, and sodium can be removed using various binders.

What is the Problem?

The main problem facing researchers in this area is the removal of urea. Twenty gms of urea have to be removed in 24 hours to duplicate the function of a normal kidney.

Specifications: Currently, stabilized urease, charcoal, oxystarch, and oxycellulose are used in the attempt to remove urea. Urease converts urea to CO_2 and Ammonia (NH_3), while CO_2 from this reaction can be buffered and exhaled. NH_3 has to be bound by a system such as the EMS copolymer.

The effectiveness of oxystarch (oxidized starch) as a urea adsorbent is controversial--Italian scientists Giordano et al.[6] report it to be a very effective sorbent, while the work of Maxwell et al.[6] seems to contradict this.

The effective mass of the sorbent capable of removing 20 gms of urea/24 hours should be sufficiently low so that it can be included in a person's daily diet or be directly introduced into the isolated intestinal loop without an overburden. Therefore, a sorbent capable of binding 40 gms of urea/Kg of sorbent is needed if one wishes to limit the necessary mass of sorbent to 1/2 Kg per day.

But it is clear from current literature that a sorbent capable of binding 40 gms of urea/Kg. of binder is not available. The sorbents used in an unencapsulated form must function over a range of pH values (1.5-8.5) as they pass through the GI tract. Also, presence of a compound similar to the toxin intended for removal can swamp out the sorbent. Toxic effects of the sorbents themselves have to be considered in the selection of the ideal compound.

It has been found that certain microorganisms such as selenomonas ruminantium not only degrade urea, by using it as their nitrogen source, but also synthesize amino acids.[5] Therefore, cellophane tubes containing these bacteria and other binders such as charcoal can be introduced into the isolated intestinal loop (see Fig. 2).[5]

These bacteria, in the presence of glucose or fructose, could create urease and amino acids.

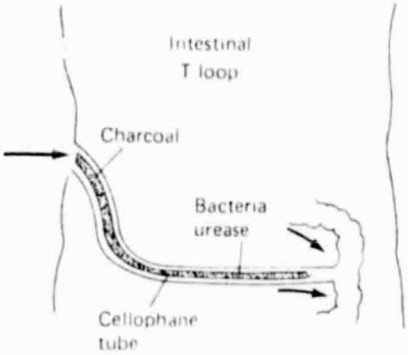


Fig. 2. *The intestinal T-loop shown in Fig. 1 further worked out.* In this instance, a cellophane tube filled with charcoal and with urease-producing bacteria is inserted into the intestinal T-loop. Urea and nutrients will reach it from the intestinal wall. Keto acids can be added, either inside or outside of the cellophane, but should not be given directly to the charcoal.

NASA Technology: Work was done under NASA research grants in the early 1960's attempting to recover potable water from urine. Several bacterial species such as Proteus Vulgaris, A. Aerogenes and Serratia Indica were investigated as to their ability to utilize various compounds associated with human urine as their main carbon and nitrogen source (N63-20248, "Biochemical Study of Mixed Culture Prototype in a Closed Ecologic System"). The results showed that only Proteus Vulgaris could convert 94-98% of urea in the urine to NH_3 and/or microbial protoplasm. This and other relevant NASA reports are being closely studied to determine the usefulness of their contents in the above application.

Actions Taken: During a recent trip to Ames Research Center, the BAT coordinator met with Dr. Vance Oyama to discuss application of NASA technology to this problem. Dr. Oyama feels that certain specific affinity polymers used in space to gather organic molecules existing at very low concentrations (parts per trillion and less) perhaps could be used in this application to attract and irreversibly bind urea. Dr. Oyama was provided with a copy of the problem statement for background information. There will be further information exchange between Dr. Oyama and the problem investigator before an accurate determination of applicability of this technology can be made.

References

1. Klein Elias, "Evaluation of Hemodialyzers and Dialysis Membranes," National Institute of Arthritis, Metabolism, and Digestive Diseases, DHEW Publication No. (NIH) 77-1294.
2. Ruchlin, H.S., and Rogers, D.C., "Economics of Health Care," Publication by Charles C. Thomas, 1973.
3. Schloerb, P.R. and Lubert, B.L., "Arch. Surg.", 86:356, 1963.
4. Clark, J.E. et al., "Trans. Amer. Soc. Art. Int. Organs," XI:18, 1965.
5. Kolff, W.J., "Kidney Int.", Vol. 10, p. s-211, 1976.
6. "Proceedings of Workshop on Gastrointestinal Sorbents in Uremia," U.S. DHEW Publication No. (NIH) 72-78, 1971.

Problem Originator: Dr. U.R. Shettigar, Institute for Biomedical Engineering, The University of Utah.

BATeam Coordinator: Bakki V. Kudva.

Problem UW-46 - Self-Contained Oxygen Supply for Use by Patients with Chronic Obstructive Pulmonary Disease

Help Wanted: Evaluate NASA technology; other NASA technology; commercialization.

Abstract: Some COPD (chronic obstructed pulmonary disease) patients require the administration of supplemental oxygen to sustain even basal activities or minimally exerting physical tasks. What is needed is a portable, easily worn device capable of supplying oxygen to these patients so they may be at least minimally ambulatory and have a more normal life.

Background: Oxygen therapy to relieve low blood oxygen and breathlessness problems in patients with respiratory insufficiency has increased since its introduction in the mid-1930's. Present subject population is estimated to be in excess of 80,000 in the United States. Other procedures are employed including bronchial hygiene techniques and pursed lip breathing to control expiratory rate. It is still necessary however, in more severe cases, that the patient breathe an enriched oxygen mixture in order to sustain arterial oxygen saturation approaching 95%. Fixed location oxygen delivery systems for non-ambulatory patients are readily available, both from large compressed gas cylinders and as systems for extraction of oxygen from ambient air for delivery to the patient. Portable systems for the ambulatory or even minimally mobile patient are much more limited. Small, compressed oxygen cylinders with their attendant regulator and other accessories are quite awkward to wear by the patient, particularly the elderly, and offer very limited storage capacity. Chemically bound sources such as the chlorate candles suffer the same disadvantage of short delivery time and, additionally, have relatively high costs compared to other oxygen sources, as well as potential ignition

hazards in the presence of hydrocarbon vapors. As a result, the most commonly used system for semi-ambulatory COPD patients is a small dewar delivery system which contains liquid oxygen. Such systems are sold by Linde and others. These systems will provide up to four hours mobility using a release rate of two liters per minute. The cost for the rental of the portable unit and fixed reservoir system is often in excess of $50 per month, not including liquid oxygen. Additionally, in all but the largest metropolitan areas, the logistics of getting liquid oxygen to the individual's home is very awkward.

The Need: The need is for an oxygen supplementation system, capable of being worn or at least easily carried by the patient and capable of supplying sufficient oxygen to permit basal activity and limited ambulation to facilitate independence from continuous care by other persons. The device should be reliable, amenable to operation by the patient, who may be elderly or have limited physical capabilities for other reasons. The system would ideally be equal to or lower in cost for annual operation when compared to existing systems. As a point of reference, a COPD patient requiring continuous administration of oxygen at an approximate flow rate of two liters per minute would incur an annual cost in excess of $3,100 per year for oxygen.[1]

Target Specifications:

1. Weight - ten pounds or less.
2. Volume - occupy a volume of less than 300 cubic inches and be so configured as to be comfortably worn by the patient.
3. The device shall deliver to the patient .75-2 liters per minute of oxygen at STP, for a period of 1-4 hours. Concentration of oxygen in the delivered gas to the patient should be greater than 90%.

4. The system shall be suited for use with a nasal cannula delivery system.
5. The system would ideally incorporate the capability of demand operation, in which the administration of the oxygen is controlled by the patient's inspiration/expiration cycle, so as to minimize oxygen consumption.
6. The source of oxygen delivered to the patient or the supplies from which the oxygen is generated or extracted should be available readily throughout the United States, or a scheme for widespread distribution widely established.
7. Cost of purchase/lease and operation of the device and its requisite supplies should be less than the cost of existing portable liquid oxygen delivery systems.
8. The design of the device shall be such that its routine operation, supply replenishment, preventive maintenance and cleaning shall be capable of being conducted by the patient himself after training.

Action Taken: A literature search has identified two potentially applicable technologies for the wearable oxygen supply system. Contact has been made with Pat McLaughlan of Crew Systems at JSC to explore possible use of a high pressure, compact storage tank developed for the firefighters breathing apparatus. Additionally, the oxygen enrichment system using molecular sieves, developed for use by military aircraft for Wright Patterson AFB, may be potentially amenable to this application. Contact was made with Bendix Instrument and Life Support Systems in Davenport, Iowa, developer of the aircraft system. While Bendix technical staff thought that there might be merit in feasibility investigation of a wearable unit,

marketing considerations resulted in focus upon an AC line-powered unit (weight limit 41 Kg) for home use (see Figure 2) to extract oxygen. This interaction did, however, result in the provision to the Regional Chest Center, of a prototype demand cannula system (see Figure 1) for potential use with a wearable system.

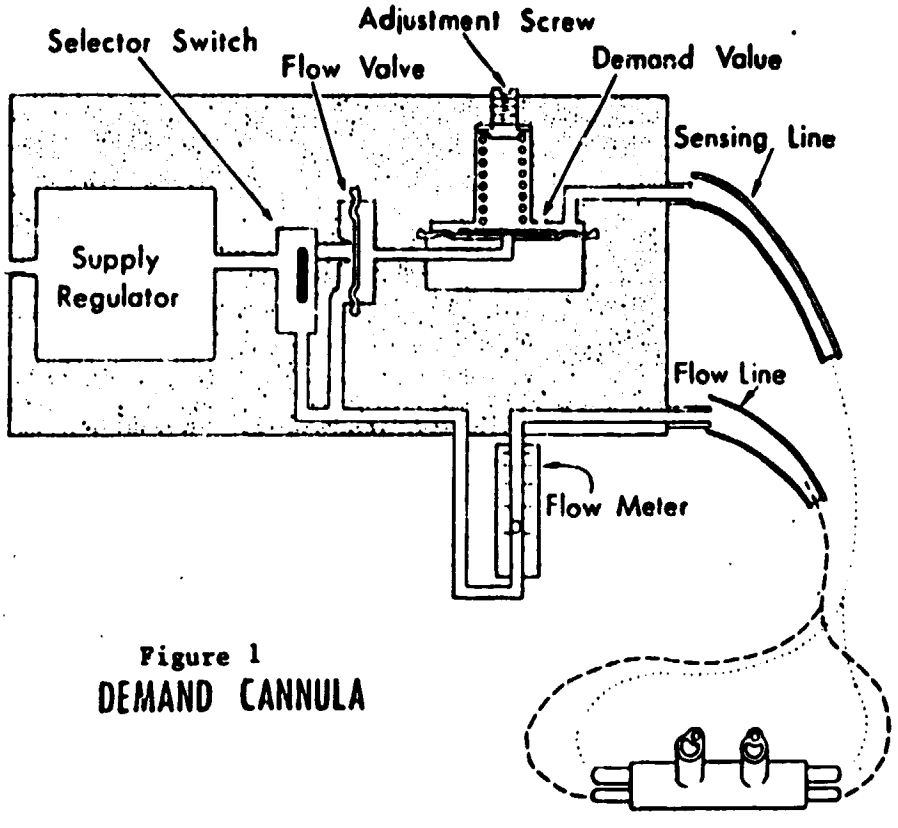


Figure 1
DEMAND CANNULA

Contact was made with Mr. Norm McCombs, President of Xorbox Corporation of Buffalo, New York. He indicated that Xorbox was quite interested in the proposed product concept and had expertise in molecular adsorption systems.

Another approach identified resulted from work done by Hamilton Standard under contract to NASA. A wearable oxygen storage system, utilizing high pressure cylinders, was constructed in a feasibility investigation. Efforts are underway to obtain loan of the prototype for evaluation by Dr. Kass at the Regional Chest Center.

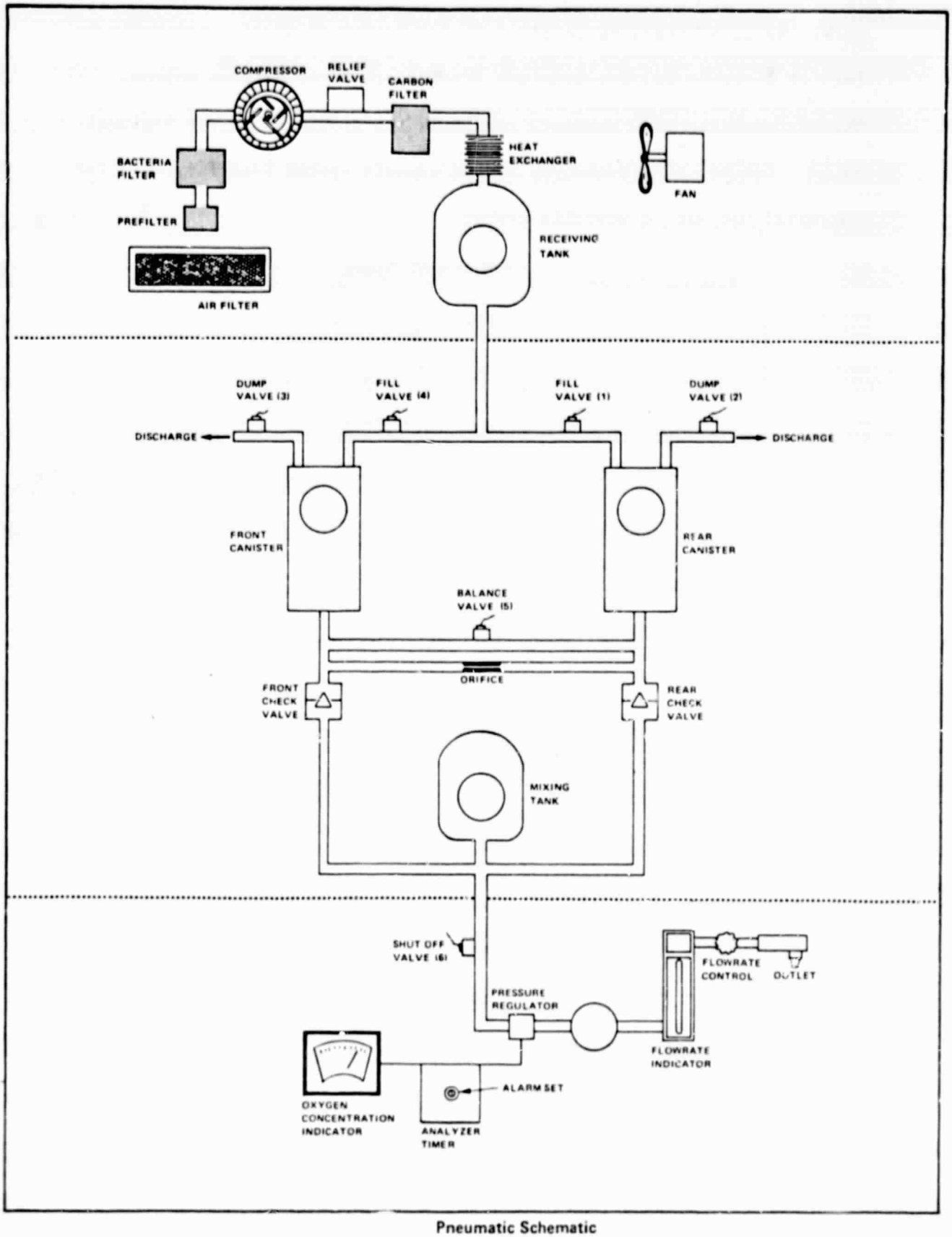


Figure 2
Molecular Sieve Oxygen Enrichment System

References:

1. Auerbach, D, Flick, M.R., and Block, A.J., "A New Oxygen Cannula System Using Intermittent Demand Nasal Flow," Am. Rev. Respir. Dis., 115:106, 1977.

Problem Investigator: Dr. Irving Kass, Director, Regional Chest Center, University of Nebraska Medical Center, Omaha, Nebraska.

BATeam Coordinator: James C. Houge

Problem UW-47 - Hand and Foot Warmers for Patients with Raynaud's Syndrome

Help Wanted: Appropriate medical specialty; commercial products available; actual extent of the problem (market size).

Abstract: The local vasoconstrictor reflex that occurs normally during exposure to cold becomes hypersensitive, mostly in the hands, of persons with Raynaud's syndrome. Complete protection from cold is essential to prevent excessive tissue damage. NASA space-suit technology is clearly applicable. Comfort Products, Inc., a company that manufactures hand and foot warmers (derived from NASA technology) for winter recreational activities such as skiing, has shown a great interest in extending this technology to this clinical application.

The Need: Raynaud's syndrome is a condition in which exposure to cold environments of various intensities, depending on the severity of the condition, or emotional disturbances causes complete interruption of the local blood flow by tight constriction of the arteries of the hands. A study by Maricq et al.[1] shows that when the hands of patients with Raynaud's syndrome are cooled to 16°C, there is a complete standstill of blood flow even at the capillary level, as compared to normal subjects in whom capillary flow is never interrupted even at much colder and longer cold exposures. As a result of this, patients with Raynaud's syndrome exhibit the classic triphasic color response in their hands when exposed to cold; hands first turn white, then blue, and finally red. The hands turn white initially due to the blood flow interruption, following which hyperemia (the buildup of metabolites) in the tissue gives them a blue tinge. The hyperemia subsequently triggers a hyperdilation of the blood

vessels causing the redness and severe pain. Continued exposure to cold can cause the fingers to become gangrenous.

Up until this year, two separate disease entities had been defined as showing the Raynaud's syndrome. These were Raynaud's disease, which was thought to be a harmless, benign condition of unknown etiology, and Raynaud's phenomenon, where the vasospasm occurred due to some underlying systemic, immunologic, or connective tissue disorders. Advances made in immunology have made it possible to show that latent disturbances in the immunologic system also exist in patients with Raynaud's disease and that these persons run a high risk of having diseases that cause Raynaud's phenomenon.[3]

Some of the conditions that cause Raynaud's syndrome are rheumatoid arthritis, dermatomyositis, scleroderma, systemic lupus erythematosus (SLE), and occupational trauma, such as caused by excessive use of hands in rowing a boat and operating pneumatic drills.

Rheumatoid Arthritis is a chronic disease of the joints marked by inflammation of the cartilage surfaces and atrophy of bones. It is estimated that this condition is responsible for more absence from work and lower industrial productivity than any other single disease throughout the world. It can strike anyone at any time in his life. About 70% of those afflicted are in the 30-70 age group. In North America, the incidence is 0.5-3.8% of all women and 0.15-1.3% of all men.[2] There is evidence of autonomic nervous system dysfunction. Moving to a warmer climate is recommended as part of the treatment. Although the exact percentage of patients that get Raynaud's syndrome due to rheumatoid arthritis is not available, all arthritis patients could be benefitted from heated gloves or garments to relieve discomfort and pain.

Dermatomyositis is a condition in which there is inflammation of skin, subcutaneous tissue, and muscles with the breakdown of muscle fibers. It occurs mostly in the age group of 20-40 years. In the acute form it could be fatal in a few weeks, but generally the disease becomes chronic after relapses and remissions, and mortality is still high. About one-third of all patients exhibit Raynaud's syndrome.

Scleroderma is a disease causing hardening of the connective tissue of any part of the body including skin, heart, esophagus, kidney, and lungs. Females are more frequently affected. An estimate of persons in the United States with scleroderma is not available.

Systemic Lupus Erythematosus (SLE) is a disease that predominantly afflicts women. In SLE, antibodies to DNA and cellular nucleic proteins are formed by invading microorganisms or from the cells' own nuclear components. The prevalence is 2-3/100,000.[2] The outcome of the disease is usually fatal.

Even though a close estimate of the number of persons that could be benefitted by the hand warmers is hard to compute from the above discussion, it should be apparent that the number is large.

Specifications: Due to different thresholds of different patients to cold, the heat output of the hand and foot warmers should be variable. Exact amounts of heat output necessary will depend upon the patient, the insulation in the glove, and environmental conditions. Thus, they would have to be designed for use with a variety of patients over a wide range of ambient temperatures. Wounds heal slowly and infection is hard to control in Raynaud's syndrome[4] so the gloves should be designed to protect the hands from injury. The power pak for the gloves and the foot warmer must be light and wearable with auxilliary inputs for power from an automobile or

boat (cigarette lighter adapter) or the domestic 110 VAC line. The batteries themselves should last at least one hour under maximum demand. Cosmetic appearance and comfort are also important design considerations.

Exact design specifications will have to be determined through use of the gloves by patients and systematic data gathering.

NASA Technology: Comfort Products, Inc., Aspen, Colorado, is a company that manufactures heated gloves and boots, derived from the NASA space suit technology, for recreational skiing and other winter activities. The BATeam coordinator contacted Mr. Dixie Rinehart, the designer of the NASA space suit, now an employee of Comfort Products, Inc. He indicated that their company is very much interested in this clinical application of the space suit technology and, in fact, Comfort Products had even done some preliminary work in the area.

Actions Taken: One pair of the heated gloves were donated by the company to be tried out by a Raynaud's disease victim in Milwaukee, Wisconsin. These gloves, called the "Lunar Mitts," were designed to be used by healthy persons during winter recreational activities such as skiing. The patient found the gloves to be inadequate for the following reasons.

The gloves contain the heating element only on the inside surface of the fingers and rely on the normal blood circulation to distribute the heat throughout the hand. This also acts as a heat sink to keep the temperature of the heating element around 80°F. Blood flow in the hands of a Raynaud's victim is reduced to <30% of normal flow.[5] So the patient found that the back of her hands were too cold, while the heating element temperature rose to the threshold of pain, due to improper heat distribution and heat sinking.

The BAT was contacted by Dr. Don Warren of the Wisconsin Foundation for Applied Technology, Inc., a non-profit organization interested in technology

application in health care, with regard to this problem. Dr. Warren, under a grant from the Wisconsin State Division of Vocational Rehabilitation is developing heated gloves for the very same application. Due to common objectives, the BAT will work jointly with Dr. Warren's group and Comfort Products, Inc., in any further developmental work.

The gloves have been currently loaned to Dr. Warren for further evaluation on another patient, a state employee in Green Bay. The data gathered will be used to develop specifications for the new design.

A NASA literature search on thermal insulation has turned up several leads on NASA technology used in space suits and gloves which will be pursued during the next quarter.

Market Study: Due to lack of information on the incidence of Raynaud's disease, a preliminary market survey was done by the BAT coordinator. The following people/institutions were contacted for patient information.

Person/Institution	Reported Cases of Raynaud's Disease/1976	
	Inpatient	Outpatient
Dr. Marguerite Lerner Yale Univ. School of Medicine New Haven, Connecticut	N.A.	24
Dr. George M. Gura Mayo Clinic Rochester, MN	N.A.	336 (1974)
Dean Clinic, Madison, WI	N.A.	36
Univ. of Wisconsin Hospitals Madison, Wisconsin	5	N.A.
Madison General Hospital Madison, Wisconsin	3	N.A.

From this mini-survey, it is apparent that the majority of patients get treated as outpatients. Only very few patients, in whom the primary disease progresses to a critical stage, get admitted as inpatients.

Both Dr. Gura and Dr. Lerner felt that there would be a good number of patients who would be benefitted by heated gloves. To obtain more information on the incidence of Raynaud's disease on a nationwide basis, a computer data search has been initiated through the Wisconsin Bureau of Health Statistics—cooperative Health Data Project.

Bibliography

1. Maricq, H.R. et al., "Standstill of Nail Fold Capillary Blood Flow During Cooling in Scleroderma and Raynaud's Syndrome," Blood Vessels, 13:338, 1976.
2. Harrison's "Principles of Internal Medicine," McGraw Hill, Seventh Edition, 1974.
3. Porter, J.M. et al., "Clinical Significance of Raynaud's Syndrome," J. Cardiovas. Surg., 18, 101, 1977.
4. "Current Medical Diagnosis and Treatment," Ed - Kupp, M.A., Chatton, M.J., Lange Medical Publications, 1974.
5. Peacock, J.H., "Comparative Study of the Digital Cutaneous Temperatures and Hand Blood Flow in Normal Hand, Primary Raynaud's Disease and Primary Acrocyanosis," Clinical Science, 18:25, 1959.

Problem Originator: Dr. Robert Mallien, American Red Cross, Milwaukee, WI.

BATeam Coordinator: Bakki V. Kudva.

Problem UW-48 - Treadmill for Home Use by Patients With Chronic Obstructive Pulmonary Disease

Abstract: Rehabilitation programs for persons with chronic obstructive pulmonary disease (COPD) involves, as an aspect of the regimen, the use of graded exercise in order to maintain and improve pulmonary efficiency in these patients. A low-cost, powered treadmill would allow such exercise to be carried out conveniently and effectively in the home.

Background: Rehabilitation programs for a variety of disabilities including COPD and cardiac disease have become increasingly widespread over the last 20 years. An expression of this has been the increase in the popularity of jogging, development of consumer products such as low-cost rowing machines, bicycle exercisers, and non-powered treadmills. Many of these devices are primarily used by persons not involved in a medically supervised conditioning program, and the exercise tolerance and work expended are often quite subjective.

It has been shown[1] that close compliance with a graded exercise program is necessary for the long-term improvement of COPD patients, who number more than 500,000 in the United States today. Studies have shown[1] that compliance with prescribed exercise using activities such as infrequent walking in the patient's neighborhood achieves the degree of improvement desired. Factors such as the weather, terrain and condition of sidewalks, etc., however, introduce too much variability into such a program.

The inexpensive devices presently available for exercise, because of their construction economy, are not suitable for such a controlled exercise program because it is not possible in the home to either calibrate

or maintain calibration of rate and quantity of work done using the extremely simple absorption loading systems typically employed. The wide variation in patients' characteristics and high average age indicate that a device such as a treadmill would be preferable to a device such as a bicycle exerciser because the treadmill would be easier to use and has the advantage that larger groups of muscles can be exercised than is possible with the bicycle exerciser.

The Need: A low-cost, reliable treadmill for use by COPD patients in graded exercise programs in their homes is needed. The treadmill would ideally require very simple operation and minimum maintenance by the patient in order to maintain proper function.

Target Specifications:

1. Treadmill speed range: 1.5-4 miles per hour. Speed may be fixed at 2 mph or optionally adjustable.
2. Elevation shall be adjustable from 0 to 20° from horizontal. Adjustment may be accomplished by bolting/unbolting or minor disassembly.
3. The flat walking surface of the treadmill shall be a minimum of 18 inches wide and 42 inches long.
4. Handrail assembly shall be readily demountable or permit folding for storage to transport.
5. Weight of the treadmill assembly shall be less than 125 pounds.
6. The device shall not require preventive maintenance or adjustment beyond the capacity of the patient more frequently than every six months. Design service life shall be at least 800 hours.
7. Selling price of the treadmill should be less than $300.

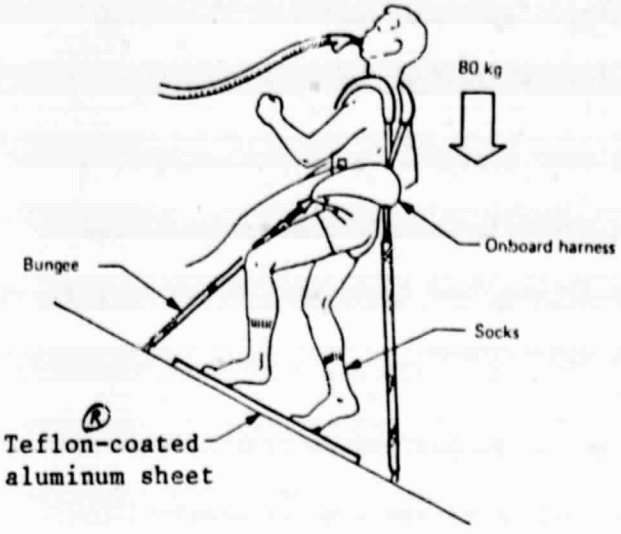
8. The device shall require only 110 volts A.C. for operation and consume less than 600 watts during operation.
9. Sound produced by the treadmill shall be less than 70 dbA.

Action Taken: A major cost component of the treadmill is the motor and its attendant costs. Minimizing the frictional losses of the treadmill will permit use of a smaller, lighter, and less expensive motor and drive assembly consuming less energy. Coating of the support pan over which the treadmill belt passes would minimize frictional losses and reduce size, weight, and energy required.

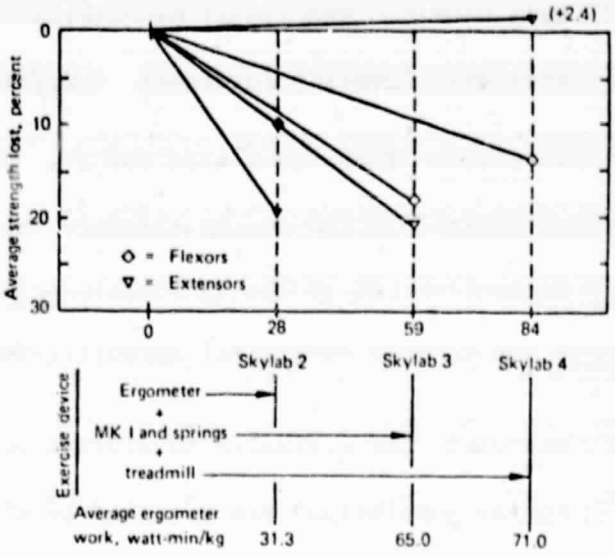
A literature search has identified a technique developed for NASA for applying a very hard, permanently lubricating coating to metals. This method was utilized to solve the problem of the bellows for the Lunar Orbiter camera "freezing" due to friction. It was also used on drills used to obtain core samples from the lunar surface. This coating process is commercially available from the General Magaplate Corporation, Linden, New Jersey.

The need for an exercise treadmill on Skylab 4 resulted in the design of a simple, easily stored system which utilized teflon bonded to aluminum to reduce friction on the walking surface. This system was used successfully and played a significant role in maintenance of the crew leg muscles. An adaptation of the elements of this system seem promising for a low-cost device for graded exercise.

The specifications have been reviewed by medical personnel in several areas of the country, and the target specifications refined and expanded to encompass all required functions and constraints. Intent has been expressed by two commercial concerns. One of these companies, Uniwave Inc., of Elmhurst, NY will be coming to Madison in January 1978 to discuss construction of a prototype treadmill for evaluation of the concept.



Treadmill arrangement (used on Skylab 4).



Average strength changes, leg.

Reference:

1. Kass, I., Dyksterhuis, J.E., Rubin, H., and Patil, K.D., "Correlations of Psychophysiological Variables with Vocational Rehabilitation Outcome in Patients with Chronic Obstructive Pulmonary Disease," CHEST, 1975, 67, 433.

Problem Investigator: Dr. Irving Kass, Director, Regional Chest Center, University of Nebraska Medical Center, Omaha, Nebraska.

BATeam Coordinator: James C. Houge.

Problem UW-49 - Sleep Monitoring Systems

Help Wanted: EEG signal processing technology, spectrum analysis, recording devices. Identify interested companies, complete design, arrange funding.

Abstract: There is a need for a simple to use, inexpensive system capable of monitoring EEG during sleep in the home environment. Technology developed to monitor EEG of the astronauts prior to, during, and after the Skylab mission seems to have commercial potential in this application.

The Need: An estimated 30 million people in the United States (15% of the entire population) are troubled by sleep disorders of one kind or another.[2] Sleep research, for the first time, is gaining worldwide recognition as a new clinical discipline (clinical polysomnography). Sleep disorders are being studied, defined, and treatment regimens evolved. Sleep research centers, being established in hospitals, have risen in numbers from 7 to 20 since 1970.[2] Pharmaceutical companies have been developing products to alleviate sleep disorders, the total market size of which is estimated at $350 million.

The mainstay of sleep research has been the monitoring of brainwaves (EEG) ever since the first classification of the electrical activity of the brain by Loomis, Harvey & Hobart in 1935.[3] Sleep is classified into various stages, the determination of which is based on the combined information from EEG, EOG (electro-oculogram) and EMG (electromyogram). While EOG indicates the activity of eye muscles, EMG is a measure of skeletal muscle activity. The characterization of sleep stages can be summed up as shown in Table 1.

Total sleep time and other major sleep parameters change with age and sex. Progression of sleep in a normal young adult is shown as sleep stage versus time in Figure 1. Voluminous data have been generated in the study of these variables.[3,4] Since 1935, there has been a large accumulation

Table 1

State	Activity: EEG Composition — Predominant		EMG	EOG
Awake	α Waves 8-14 Hz	β Waves 15-35 Hz	High	High
Stage 1	β Waves	α less than 50% of above; θ Waves 4-7 Hz	Low	Low
Stage 2	θ Waves	Spindles 12-14 Hz bursts 0.5 secs.; K-complexes	Low	Low
Stage 3	δ Waves 0.5-3 Hz	Reduced θ		
Stage 4	δ Reduced 50%			
REM (Restless Eye Movement)		Same as Stage 1	Low	High

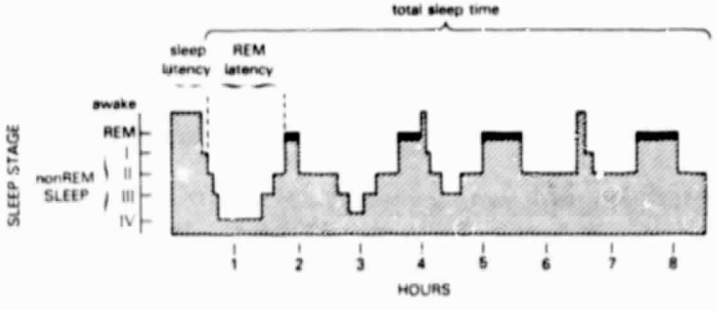


Figure 1
Progression of normal sleep in a normal young adult.

of research data pertinent to sleep disorders, now termed dyssomnias. Some of the more common disorders are described below.

Insomnia is by far the most common sleep disorder. At the December 1976 sleep conference in New York, the results of a 3,000 physician survey gave insomnia the top billing as 18.7% of all dyssomnias. Insomnia is widely known as the inability to sleep in a normal environment.

Sleep Apnea is a disease where the victim stops breathing during sleep for 20-130 seconds, forcing him to awaken. This can happen as many as 500 times during the night.[2] Most patients have such brief breathing interruptions that they have no recollection of these episodes in the morning except for daytime sleepiness, hallucinations, personality changes and abnormal behavioral outbursts. Sleep apnea affects more than 50,000 Americans.[1,2] Sleep apnea is believed to be one of the causes of SIDS (sudden infant death syndrome).

Narcolepsy is a disease where patients are subject to irresistable and overpowering daytime sleep attacks. The BATeam coordinator contacted Bill Baird, President of the American Narcolepsy Association. According to Mr. Baird, there are 250,000 narcoleptics in the United States by conservative estimates.

There are many other dyssomnias, the discussion of which would be beyond the scope of this statement. Dyssomnias can occur secondary to other disorders such as renal insufficiency, nutritional disorders, thyroid dysfunction, neurologic disorders, brain and spinal column lesions or tumors, infectious conditions and mental retardation.

Sleep monitoring can help doctors to see if the problem is primary, i.e., caused by an abnormal physiology or whether it is secondary, a result of psychiatric or emotional problems.

Monitoring at Home Versus in Hospital

Both have their relative merits and disadvantages. Monitoring sleep in a hospital allows the use of sophisticated equipment, expert medical personnel and other medical services. However, it is very expensive, space limited, and the change in the environment can make the patient anxious and compound his problems at least for the first few days.

It is our hope to develop a simple-to-operate, home-based EEG data acquisition system enabling the patient himself to gather the data to be processed by his clinical somnologist at a sleep center. Preliminary talks with the professionals in this field show that such a system can have a high market potential in view of the growing recognition of dyssomnias. The reduced cost of home monitoring can make diagnosis and treatment available to a much greater section of the patient population.

NASA Technology

Sleep monitoring techniques for Skylab astronauts were developed with a similar purpose. They had to be simple to use by the astronauts, non-intrusive and designed for remote processing of the data. A sleep analysis system designed by NASA for study of sleep in normal adults during space flight is described in the "Skylab Sleep Monitoring Experiment (M133)" by Dr. James D. Frost et al.[5]

> ". . . The complete sleep-analysis system designed for this experiment included data-acquisition hardware, onboard analysis components, and a capability for real-time telemetry."
>
> "Onboard equipment accomplished automatic analysis of the electro-encephalogram, electro-oculogram, and head-motion signals. The system's output, consisting of sleep-stage information, was telemetered in near real time to Mission Control, where a profile of sleep state versus

time was accumulated. The analog signals (electroencephalographic, electro-oculographic, and head motion) were also preserved by onboard magnetic-tape recorders, thus allowing a more detailed post flight analysis."

"The components for the hardware are shown in Figure 2. (The figure numbers were changed for this problem statement--ed.) The astronaut wore a recording cap containing electrodes for detecting electroencephalographic and electro-oculographic activity. A preamplification unit, attached to the cap near the vertex of the head, amplified the signals, and a dual-axis accelerometer, housed within the preamplifier, provided information concerning movement of the subject's head. A flexible cable connected the preamplifier with a control-panel assembly . . . containing additional circuitry that accomplished automatic electrode testing, sleep analysis, and generation of the telemetry output signal, indicative of the subject's current level of consciousness. Two tape recorders, attached to the rear of the control-panel assembly, provided an analog record of the subject's sleep."

"The recording cap (Figure 3), made of an elastic-type fabric, stretches to conform comfortably to the subject's head. Inside the cap, sponge-type electrodes are attached at the positions necessary for acquisition of electroencephalographic and electro-oculographic signals; wires join the electrodes to a miniature electrical connector at the vertex of the cap, enabling rapid linkage with the preamplifier/accelerometer assembly."[5]

A block diagram of the Skylab monitoring system is shown in Figure 4, which is self-explanatory. When the sleep stage information from the automatic analyzer is plotted against elapsed time, a sleep plot is generated

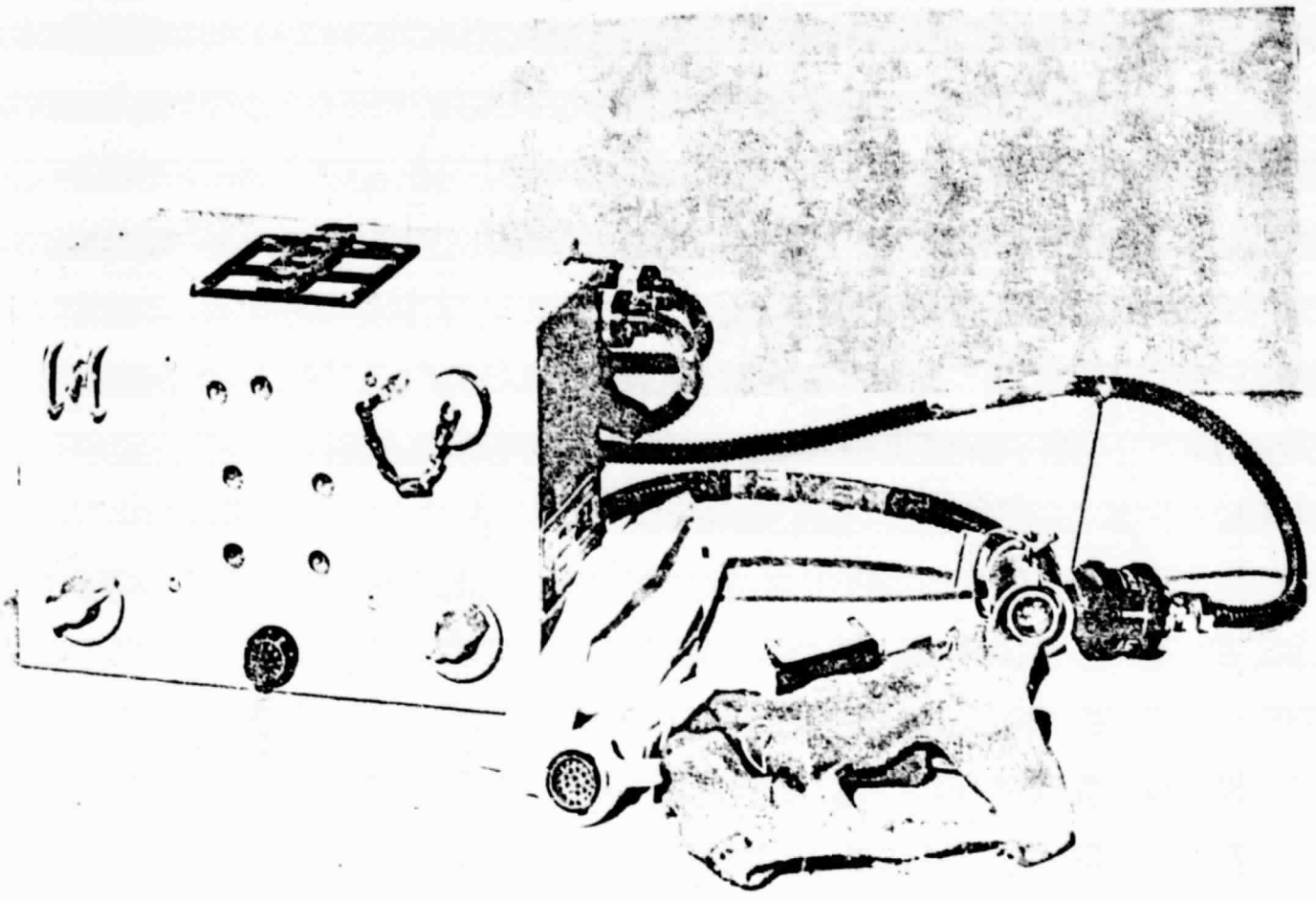


Figure 2. Skylab M133 sleep monitoring experiment hardware: control-panel assembly (left) recording cap and preamplifier unit (lower right).

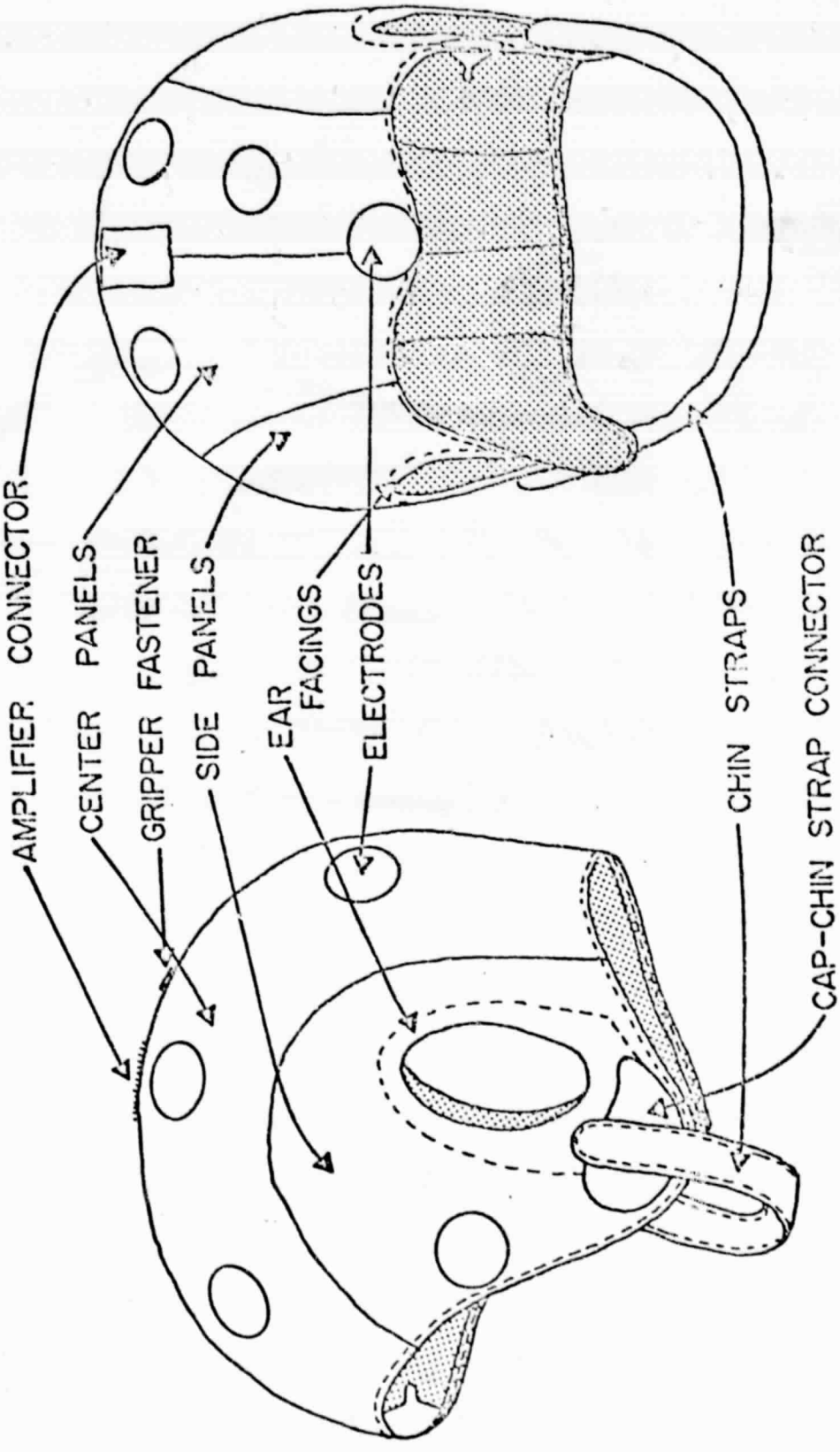
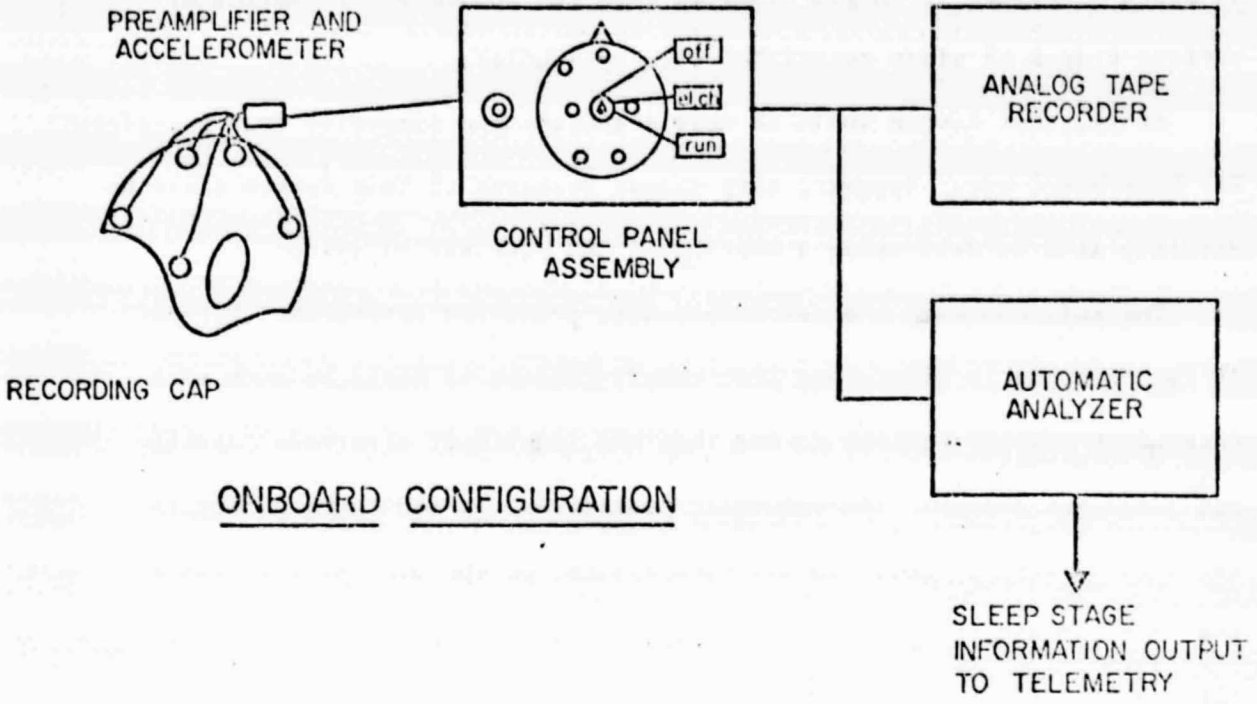


Figure 3. Cap Construction.



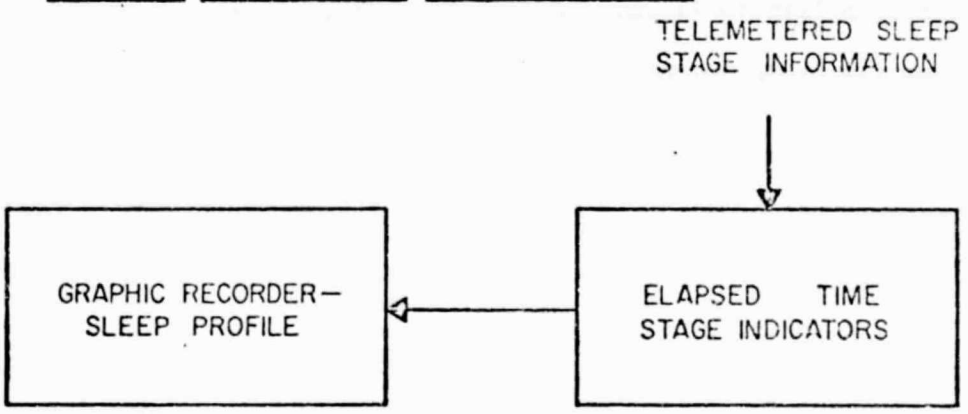


Figure 4. Block Diagram of Sleep Monitoring System.

as shown in Figure 5. A plot such as this can indicate deprivation of various stages of sleep associated with dyssomnias.

As is, this system would be more elaborate and expensive than necessary for home-based use. However, many unique features of this system could be directly used in developing a home-based EEG acquisition system.

The soft cap with the new disposable, prefilled electrodes (TSP-MSC-14623, "Disposable Biomedical Electrode") (Figure 6) would be much more convenient for the patient to use than the individual electrode locating and placement design. The automatic electrode function testing feature can also be very useful. In the NASA system, as the astronaut activates the test circuit, a small current (approximately 10 μA) passes in succession through the single ground electrode to each of the recording electrodes. In this manner, inter-electrode resistance is determined. If a given electrode has achieved proper scalp contact (resistance 50,000 Ω or less), the lamp corresponding to that electrode is illuminated. Improper contact is indicated by failure of a lamp to illuminate, and the subject corrects this by gently rocking the electrode in question from side to side to position the tip through the hair.[5]

A preliminary design for a home-based system developed from these concepts is shown in Figure 7. The final form, of course, would evolve from joint efforts among clinicians, NASA scientists, and industry. A microprocessor based "intelligent system" is indicated for versatility and simplicity.

Actions Taken: The BATeam coordinator contacted Dr. Charles Pollack, Dept. of Neurology, Sleep/Wake Disorders Unit, Montefiore Hospital, New York; Dr. James Frost, Principal Investigator of Skylab sleep monitoring experiment; and Mr. Bill Baird, President of the American Narcolepsy Foundation. All three have shown great interest in this proposed project.

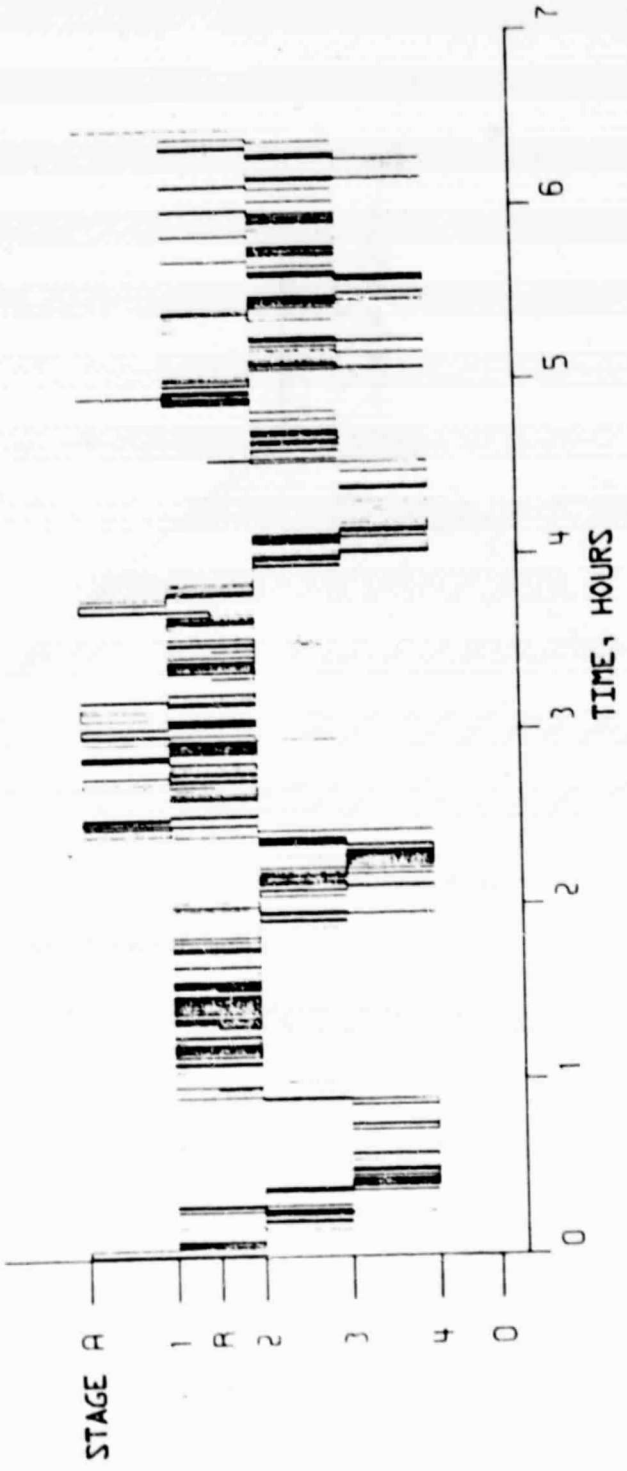


Figure 5. Sleep plot generated by computer: Scientist Pilot, day 21 of the 28-day mission.

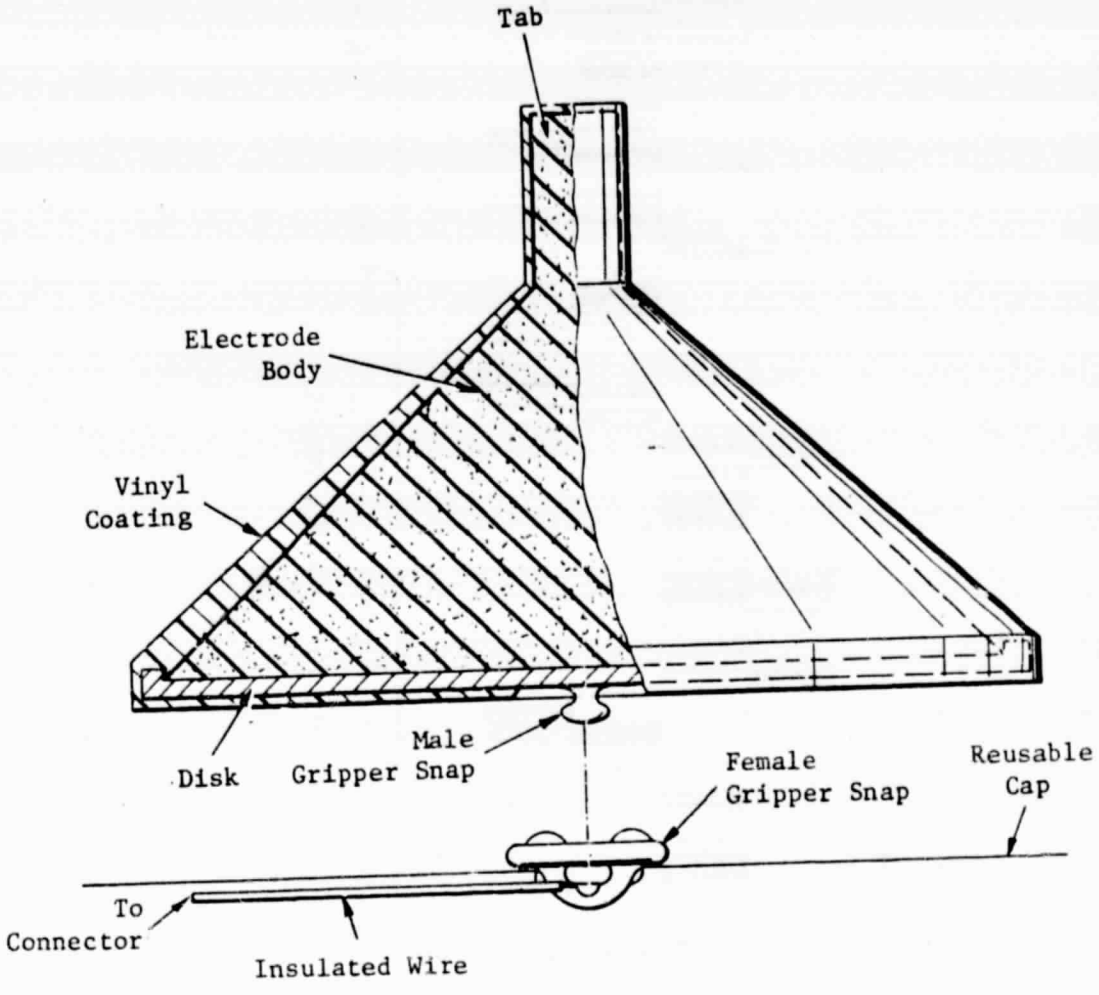


Figure 6. Disposable Electrode Assembly

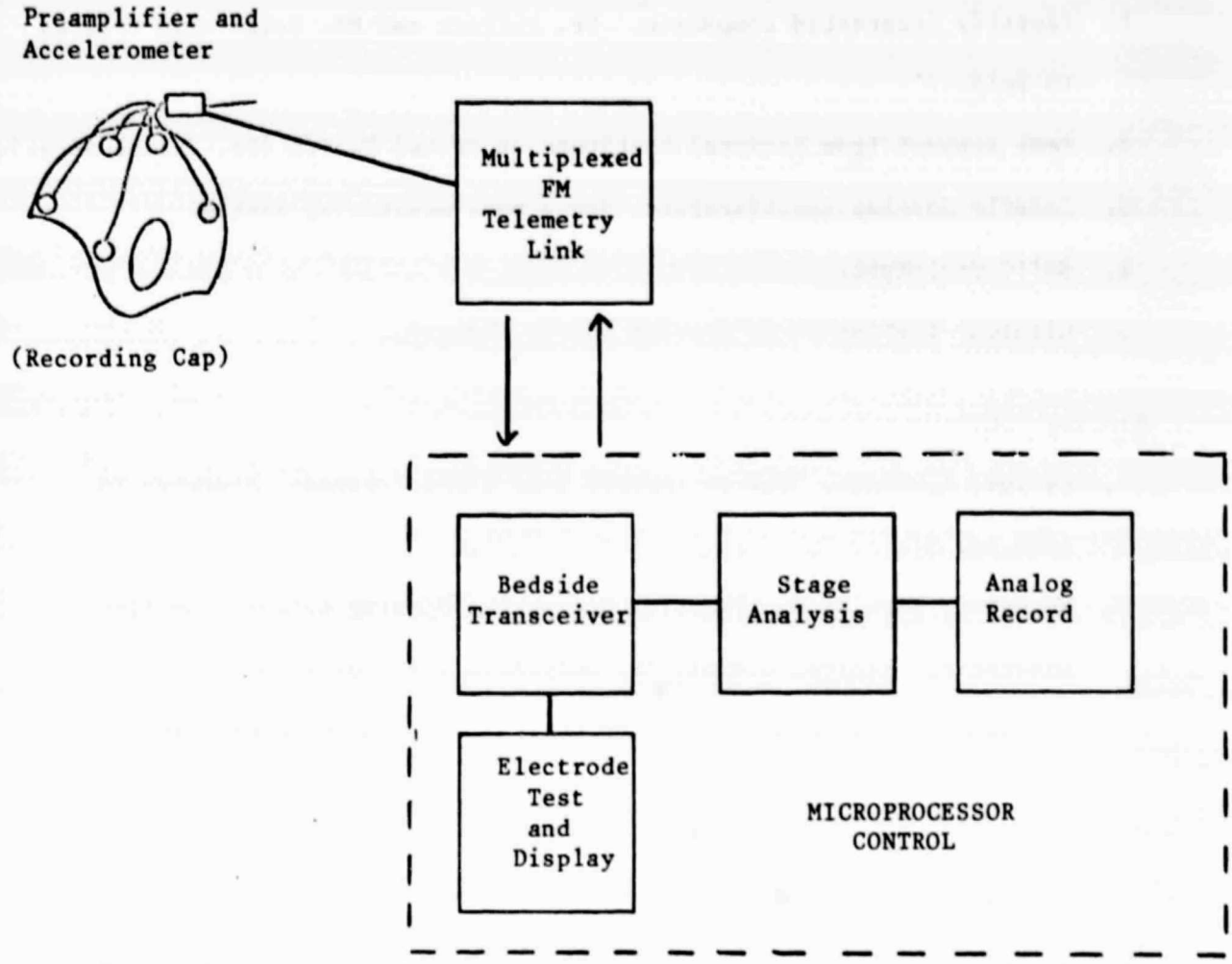


Figure 7. Block Diagram of Proposed Sleep Monitoring System.

Future Plans:

1. Identify interested companies. Dr. Pollack and Mr. Baird have offered to help.
2. Seek support from National Institute of Mental Health (Dr. Julius Segal).
3. Jointly develop specifications for a home monitoring system.
4. Build prototype.
5. Clinical testing to be carried out by company.

Bibliography

1. Galton, Lawrence, "How to Improve Your Sleep," Parade, November 20, 1977, p. 17.
2. Mosesson, Bernice K., "Bedtime Story--Eye Opening Research on Sleep Disorders," Medical Dimensions, July/Aug. 1977, p. 20.
3. Williams, R.L., Karacan, I., and Hursch, C., "EEG of Human Sleep: Clinical Applications," John Wiley & Sons, 1974.
4. Mendelson, W.B., Gillin, C.J., and Wyatt, R.J., "Human Sleep and its Disorders," Plenum Press, 1977.
5. Frost, J.D. et al., "Skylab Sleep Monitoring Experiment (M133)," The Skylab Life Sciences Symposium, August 27, 1974.

BATeam Investigator: Dr. Charles Pollack, Dept. of Neurology, Montefiore Hospital, New York, NY.

BATeam Coordinator: Bakki V. Kudva.

Problem UW-50 - Improved Device for Treatment of Esophageal Achalasia

Help Wanted: Evaluate NASA technology; other NASA technology; identify interested companies.

Abstract: Esophageal achalasia, or failure of the gastroesophageal junction to relax, is successfully treated in some patients without surgery by dilatation of the junction with an inflatable bag. Current dilators do not adequately monitor the degree of dilatation, with the resultant possibility of esophageal perforation. A safer method of dilatation therapy to be used in the management of achalasia is needed.

Background: Esophageal achalasia is characterized by a failure of relaxation of the gastroesophageal junction, the absence of peristalsis from the body of the esophagus, and the progressive dilatation of the body of the esophagus which becomes a reservoir for undigested food (see Figure 1). Achalasia is treated by dilatation or surgery. A mercury-weighted bougie may be used to dilate the esophagus up to #60 Fr, producing temporary and incomplete relief.[1] This can be used to improve esophageal drainage until the patient can be offered more effective bag dilatation or myotomy at a later stage.

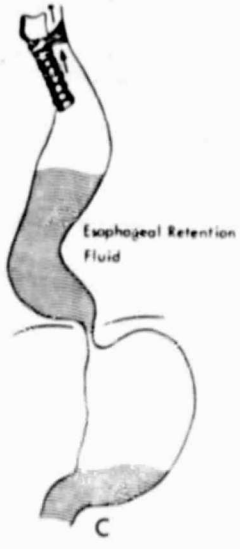
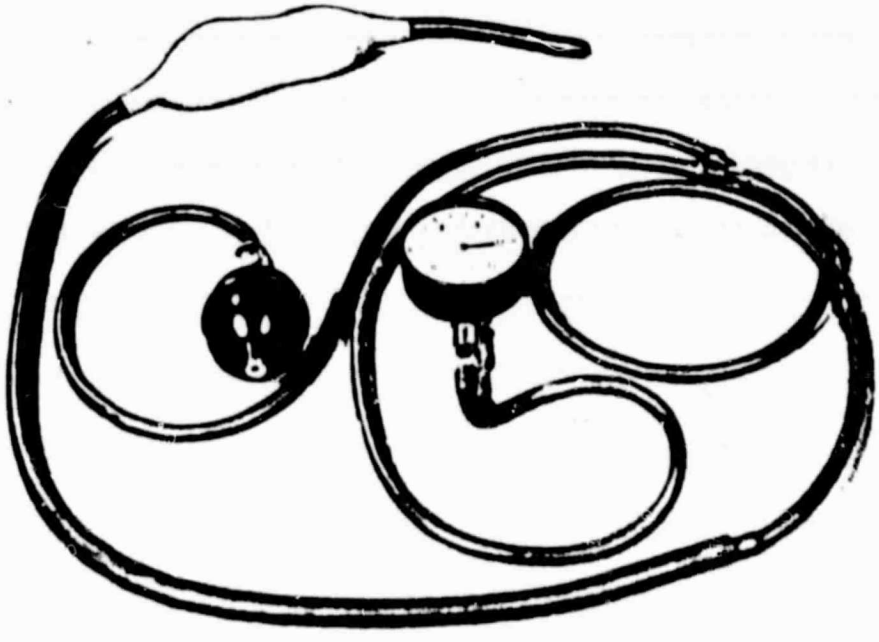


Figure 1. Esophageal Achalasia

Bag dilatation was first described by Russell in 1898.[2] An adaptation of this water system, the Browne-McHardy air distension bag, was described in 1939[3] and is still in common usage (see Figure 2). The pictured device has been essentially in use for almost 40 years. The manufacturer reports a continuous sale of approximately 4 of the $500 units per month. The bags are usually used as either fully dilated or not dilated. The bags are typically 45-50 mm in diameter with a pressure of approximately 9 PSI when fully dilated.

Since the early 1900's, forceful dilatation has been the conventional mode of treatment for esophageal achalasia. Because good results are achieved in only 65% of patients with significant complications in 5%, surgical treatment has been used more frequently and with considerable success. There



Browne-McHardy dilator uses air pressure in a restricted cuff to apply controlled stress to the gastroesophageal junction. The component parts are a dilator bag with restraining mesh to avoid overdistension, an air pump and a gauge. The bag is inserted under topical anesthesia and placed across the gastroesophageal junction using fluoroscopic control.

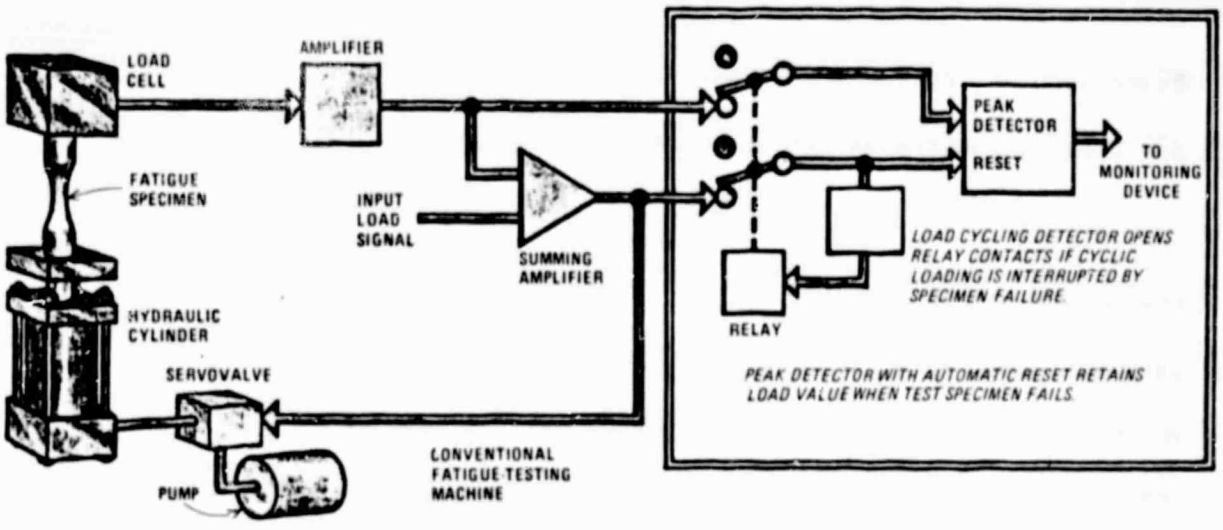
Figure 2. The Browne-McHardy air distension bag.

is, however, a class of patients not able to tolerate general anesthesia for whom bag dilitation is still the treatment of choice. The intended mechanism of dilatation therapy is to produce sufficient dilatation to tear the muscle of the gastroesophageal junction without perforating the esophagus. It is difficult with the current dilators to know when the muscle has been sufficiently torn without risking esophageal perforation.

The Need: A device or technique to safely produce relaxation of the gastroesophageal junction. Such a device would be used in patients with esophageal achalasia for whom surgery is precluded. Additionally, if the degree of muscle tearing could be more accurately monitored and the level of complications reduced, dilatation therapy would probably be used more frequently in all types of achalasia patients before surgery is resorted to.

Specifications: Dilatation of 50 mm diameter is typically required to tear the muscle of the gastroesophageal junction but is variable from patient to patient. Good data is not available so it would be desirable to have a device which monitored degree of dilatation as well as indicating when the muscle had begun to tear. At a minimum, the dilator should permit determination of the initiation of muscle tearing and prevent abrupt changes in diameter which might perforate the esophagus. The dilator should be able to exert a surface pressure of up to 12 PSI. The new device should not sell for inordinately more than the current $500 devices. A modification of an existing bag dilator which permits monitoring of bag diameter and prevents abrupt diameter changes after initial muscle tearing may be the most straightforward approach. Other approaches such as non-pneumatic mechanical dilators need not be automatically ruled out, however.

Action Taken: A search for applicable NASA technology has been initiated. It is possible that NASA strain gage and pressure transducer technology is applicable to the solution of this problem. Additionally, if a volume-driven system is used, the system shown in Figure 3, which was developed by Langley Research Center, might be used to sense peak pressure/ volume and shut down the drive, preventing the possibility of esophageal performation.



Fatigue Monitor 'Freezes' Peak Loads

■ ***Problem:*** *In material fatigue tests, the load usually recorded is the one which the test machine is attempting to apply to the specimen, not the actual load at which failure occurs. The actual failure load can be determined, but this requires an oscillograph or similar equipment to make continuous load recordings.*

■ ***Solution:*** Actual failure loads can be determined without continuous recording by applying the output of a load cell to a peak detector that disconnects when the specimen fails. Thus, the load value contained in the detector is protected. The system consists of a conventional fatigue-testing machine and the peak-detector circuit, which also includes a load-cycling monitor. In operation, the output of the load cell is applied to the peak detector and a summing amplifier. This amplifier combines the load-cell signal with the input load signal to produce an alternating output in phase with loads applied to the test specimen. This signal is fed to the load-cycling monitor and to the reset terminal of the peak detector so that for each cycle, the peak detector monitors increasing load and resets during decreasing load. If the specimen breaks or the cyclic loading is interrupted, the load-cycling monitor operates a relay that disconnects the peak detector from the load cell and summing amplifier. The system was developed by Langley Research Center.

Figure 3.

References:

1. Henderson, R.D., Motor Disorders of the Esophagus, Baltimore: Williams and Wikins, 1976.

2. Russell, J.D., "Diagnosis and Treatment of Spasmodic Stricture of the Oesophagus," Br. Med. J., 1:1450, 1898.

3. Browne, D.C. and McHardy, G., "A New Instrument for Use in Esophagospasm," Jour. A.M.A., Vol. 113, No. 22, November 25, 1939.

Problem Investigator: John F. Morrissey, M.D., Dept. of Health Sciences, Prof. of Gastroenterology, University of Wisconsin-Madison.

BATeam Coordinator: Everis R. Engstrom.

SECTION IV

ACTIVITIES AND ACCOMPLISHMENTS

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ACTIVITIES AND ACCOMPLISHMENTS

BURNS ANALYSIS SYSTEM

At the suggestion of Mr. Ray Whitten, Head of Biomedical Applications for NASA-TU, the UW-BAT assumed responsibility for the commercialization of the JPL Burns Analysis System. Preliminary discussions of the subject were carried out by phone with Dr. Victor Anselmo, the inventor of the burns system and Senior Scientist in Biomedicine at JPL. Subsequently, Mr. Burke O'Neal of the UW-BAT visited JPL on September 21-23, 1977 to inspect the burns system and plan a commercialization strategy.

It was decided that a demonstration of the system should be held for interested companies. While work proceeded at the University of Southern California Burn Center in evaluation of the system, Mr. O'Neal was to contact companies and make plans to hold the demonstration. To avoid possible conflict with patient care at the burn ward, the demonstration was to take place at JPL.

Seven large companies with products in image forming diagnostics were contacted. Of these, written interest in sending someone to the demonstration was received from three and verbal commitments from three others.

It was first decided to schedule the demonstration in late fall 1977. Subsequent difficulties encountered gathering the data at USC pushed the target date back to mid-March 1978. A report on the demonstration and on subsequent efforts to speed the commercial development of the JPL burns analysis system appeared in reports covering BAT activities in 1978.

LIXISCOPE

One of the most promising applications for the GSFC Lixiscope is in dentistry. Patients who are able to visit a fully equipped dental office are able to benefit from the use of x-ray equipment for diagnosis. But those who live in relative isolation or who are unable to visit a dentist's office, such as some of the elderly and handicapped, often must forego a comprehensive diagnostic examination. The portable imaging device, the Lixiscope, could be carried to the side of this latter population.

As a direct result of the activity generated by the UW-BAT to define needs in dentistry amenable to solution with NASA technologies, the UW-BAT accepted responsibility to help commercialize the Lixiscope, Mr. Bakki Kudva met with the inventor of the Lixiscope, Dr. Lo I Yin, and others at GSFC in May 1977 and also in October 1977 to learn about the device and plan a commercialization strategy. In November 1977, Mr. Kudva attended the Annual Meeting of the American Nuclear Society in San Francisco as part of the NASA contingent on hand at the meeting to announce the device, answer questions, and solicit industrial interest in its application.

Independent evaluation of the Lixiscope will be carried out by investigators at three separate sites: the NIH, Howard University, and Duke University. To further the commercialization of the Lixiscope, a demonstration conference is scheduled for mid-1978, at which time these investigators will present their findings. The UW-BAT will be responsible for arranging the conference. To help develop a mailing list of prospective attendees, the Team prepared a list of x-ray manufacturers in the United States and provided this information to the GSFC TU Office.

PROCTOSIGMOIDOSCOPE

At the request of Dr. Douglas A. O'Handley at the Jet Propulsion Laboratory, the UW-BAT did a preliminary investigation of the commercial potential of an improved proctosigmoidoscope, a design which resulted from a NASA-sponsored study entitled "Feasibility Study on the Design of a Probe for Rectal Cancer Detection" (JPL Publication 77-31). A mockup of the proctosigmoidoscope, developed by Mr. R. E. Frazer of JPL, was shown to provide an extremely wide angle of vision. A patent application has been filed. Each year there are approximately 100,000 new cases of and 50,000 deaths from colorectal cancer. Numerous physicians and researchers believe that there is a great need for increased mass screening for colorectal cancer. Cost-effectiveness, however, of mass screening for this disease is still controversial. One issue is that the procedure should be made more agreeable for patients. Some physicians also believe that it is important to reduce the cost of an exam by making better use of technicians. Others believe that once the patient is prepared, the exam can be completed in 3-4 minutes by a physician. Consequently, such physicians tend to object to the further use of paramedical personnel. Currently, some major clinics rely almost exclusively upon technicians to perform proctosigmoidoscopy, but the practice is not widespread.

UW-BAT personnel interviewed two former presidents of the American Society for Gastrointestinal Endoscopy and found an acute difference of opinion, both as to the need and also the potential market for an improved proctosigmoidoscope. One believed that the most time-consuming part of the procedure was proper cleansing of the bowel. Feces tends to adhere to polyps and cannot be adequately removed with an enema. The other suggested that an endoscope which provided good retrograde vision would be useful to

visualize lesions near the anal canal and for checking for hemorrhoids near the end of an exam. Both agreed that an animal test would have to be conducted before any new device is evaluated clinically.

Subsequent to the initiation of the BAT investigation, JPL decided not to pursue further development of the device at this time. Meanwhile, the California Institute of Technology has reportedly decided to apply for a waiver of patent rights to this device and plans to independently pursue licensing arrangements. The UW-BAT prepared and sent to JPL a list of eminent endoscopists interested in the evaluation of the device. Further efforts to commercialize the device will be deferred pending a renewal of interest at JPL.

* * * * *

BRIEF REVIEW OF OTHER NOTABLE ACCOMPLISHMENTS

Electrode soft caps developed for EEG monitoring of astronauts were provided to two groups of investigators for separate evaluation. These applications were for driver alertness monitoring (in the report covering last quarter 1976) and for the diagnosis of petit mal epilepsy (in the report covering first quarter 1977).

A satellite demonstration of the transmission of ECG signals from remote ambulance to a medical center was planned for the Iowa State Department of General Services. Meetings were held, under UW-BAT sponsorship, at the GSFC between representatives from the Iowa state government and the GSFC Applications Engineering Office (see quarterly reports for the second and third quarters, 1977).

Planning for a TU-RTOP on Advanced Hearing Aids for Children involved one member of the UW-BAT. A meeting involving people from several TU units as well as representatives of non-NASA federal agencies was held. Requirements were discussed and an announcement prepared for distribution to NASA field centers to solicit proposals (see report on third quarter, 1977).

* * * * *

INACTIVATED PROBLEM STATEMENTS

Title: An Unobtrusive Device for Suppression of Acoustiomotor Epilepsy
UW #: 7
Date of Inactivation: October 1977
Reasons: (a) BAT project completed.
(b) Epilepsy Foundation notified of availability of device.
(b) Commercialization unlikely.

Title: Family Practice Clinic Design
UW #: 11
Date of Inactivation: October 1976
Reasons: (a) NASA project completed.
(b) Models of patient demand and services rendered were delivered by NASA.
(c) Management tool--commercialization unlikely.

Title: Human Engineering Factors in Hospital Communication Design
UW #: 16
Date of Inactivation: December 1977
Reasons: (a) Transfer of NASA information completed.
(b) Specialized application--widespread market unlikely.
(c) No plans for further application.

Title: Early Stroke Detection
UW #: 19
Date of Inactivation: December 1977
Reasons: (a) Long, unproductive active period (two years).
(b) No NASA technology identified.
(c) Research--no commercialization planned.

Title: Abnormal Brain Wave Detection
UW #: 20
Date of Inactivation: December 1977
Reasons: (a) Long, unproductive active period (two years).
(b) No NASA technology identified.
(c) Research--no commercialization planned.

Title: Non-Silver Bearing Film for X-ray Use
UW #: 22
Date of Inactivation: December 1977
Reasons: (a) More research needed on proposed NASA solution--exposure sensitivity too low.
(b) Commercial partner could not be found.
(c) Since industrial application looks easiest, the NASA/MAT agreed to assume lead role in future commercialization efforts.

Title: Ruggedized Cable Assembly for Patient Control of Nurse Alerting and Environmental Control System
UW #: 25
Date of Inactivation: April 1977
Reasons: (a) System needing improvement rapidly going out of use.
(b) Problem with existing commercial product--new commercialization unlikely.

Title: An EEG Switch
UW #: 26
Date of Inactivation: December 1977
Reasons: (a) No NASA technology identified.
(b) Research--no commercialization planned.
(c) Similar to work being carried out by another BAT (Stanford).

Title: Unobtrusive Alertness Monitor
UW #: 27
Date of Inactivation: December 1977
Reasons: (a) Commercial solution found.
(b) NASA technology identified, but found to be inappropriate.
(c) Researcher no longer strongly interested.

Title: A Telemetry Device to Monitor Loading and Stress Patterns in Metallic Implants
UW #: 28
Date of Inactivation: April 1977
Reasons: (a) Information transfer completed.
(b) NASA technology based system is commercially available from Konigsberg Instruments on a custom-made basis.
(c) Equipment loan from Ames was not feasible.

Title: Highly Regulated Differential Temperature Control System
UW #: 29
Date of Inactivation: October 1976
Reasons: (a) Information about applicable NASA system given to investigator.
(b) Research--no commercialization planned.

Title: Improved Pump System Reliability for Extended Circulatory Bypass
UW #: 31
Date of Inactivation: October 1977
Reasons: Problem originator found alternate ways of getting around the mechanical fatigue and spallation problems found in silastic tubing.
(a) Segmented polyurethane tubings are available commercially that outlast silastic by 200 to 300% without spallation.
(b) Bio-Medicus, Inc., 15307 Industrial Road, Minnetonka, MN 55343 has started marketing a centrifugal blood pump by the trade name Bio-Pump™ that completely eliminates the spallation problem found in roller pumps due to the fact that the tubing is not subjected to compressive stresses.

Title: Reliable, Inexpensive Relative Humidity Transducer
UW #: 36
Date of Inactivation: April 1977
Reasons: (a) Problem apparently solved with commercially available device.
(b) No NASA technology identified.

Title: Home Water Filtration Device
UW #: 38
Date of Inactivation: December 1977
Reasons: (a) Problem can't be well defined yet.
(b) Commercialization impossible until non-technological issues better resolved.

Title: Absorptiometric Techniques
UW #: 40
Date of Inactivation: December 1977
Reasons: (a) No NASA technology identified.
(b) Research--no commercialization planned.

Title: Microwave Blood Warmer for Extracorporeal Circulation
UW #: 44
Date of Inactivation: October 1977
Reasons: (a) Low market potential.
(b) Technology expensive compared to conventional methods.

* * * * *

TRIPS AND CONFERENCES

Travel by members of the Team has been divided into several categories according to the primary purpose of the trip. Visits arranged to present the TU/BAT program or carry on discussions with project leaders are grouped under Presentation and Discussion. The other categories are self-explanatory. (Conference Attendance includes regularly scheduled trade or professional meetings, special workshops, and meetings for which NASA was a co-sponsor.)

A. PRESENTATION AND DISCUSSION

University of Nebraska Medical Center, Omaha, NB (October 12-13, 1976).
First visit to make contacts and establish liaisons. (Houge)

University of Illinois & Northwestern University, Chicago, IL (October 13-14, 1976).
First visit to make contacts and establish liaisons. (Kudva)

University of Iowa Medical Center, Iowa City, IA (October 21-22, 1976).
First visit to make contacts and establish liaisons. (Engstrom)

Brown University, Providence, RI; Harvard Dental School, Cambridge, MA; Peter Bent Brigham, Cambridge, MA; Children's Hospital, Cambridge, MA; Massachusetts General Hospital, Boston, MA; & MIT, Cambridge, MA (November 10-12, 1976).
First visit to make contacts and establish liaisons. (Kudva)

University of South Dakota Medical School, Vermillion, SD (November 14, 1976).
First visit to make contacts and establish liaisons. (Houge)

South Dakota State University, Brookings, SD (November 15, 1976).
First visit to make contacts and establish liaisons. (Houge)

University of Cincinnati, Cincinnati, OH; and Area Hospitals (Nov. 14-18, 1976).
First visit to make contacts and establish liaisons. (Kudva & O'Neal)

Visit with Barry Simmons, Athens, GA (December 11, 1976).
Discussions of possible applications of NASA technology in remote dentistry (UW-35). (Kudva)

Marquette Dental School, Milwaukee, WI (February 18, 1977).
Visited Dr. Robert Mallien to discuss application of NASA technology in portable dental equipment developed there. (Kudva)

University of Minnesota, Minneapolis, MN (February 25, 1977).
Presentation to the Biophysics Group and their guests, of the TU-BAT program and possibilities for future interaction. (Fetzner)

University of Nebraska Medical Center, Omaha, NB (August 4, 1977).
Contacted personnel of the UW-Regional Chest Center (Drs. Kass, Bell, Fix, and Jensen) in response to letter of inquiry from Kass to Don Vargo (KT). Investigating technology transfer opportunities in area of long-term treatment of chronic obstructive pulmonary disease. (Houge)

Meeting on Satellite Demonstration, GSFC, Greenbelt, MD (September 15, 1977).
Scheduled to bring together personnel from the Iowa Division of Communications and representatives from the Office of Applications at GSFC to consider plans for a satellite transmission of EMS communications in Iowa. (Engstrom)

George Washington University & St. Louis University, St. Louis, MO (Oct. 27-29, 1977).
Contacted staff and faculty members at the two universities to acquaint them with the BAT program and seek out problem areas for further interaction. (Houge)

Wayne State University, Detroit, MI, & University of Michigan, Ann Arbor, MI (October 27-28, 1977).
Initiate discussions regarding the UW-BAT program. Gave a talk at UM on NASA programs in biomedical technology transfer. (Fetzner)

Western Research Application Center, Los Angeles, CA (November 11, 1977).
Met with Radford King, Director of this NASA-funded organization. Purpose--explore possibilities for cooperative activities between the UW-BAT and WESRAC. (Kudva)

University of Arizona, Tucson, AZ (November 10, 1977).
Talk with physicians and others about their petit mal project--a study based upon previous work by the UW-BAT. Also met with other physicians, engineers, and scientists to generally discuss the UW-BAT program. (Fetzner)

University of Washington, Seattle, and Good Samaritan Hospital, Portland, OR (August 21-22, 1978).
Invited to meet with hospital administrators and doctors to discuss needs of elderly and handicapped. (Houge)

B. VISITS TO NASA FACILITIES

Lewis Research Center, Cleveland, OH (November 23-24, 1976).
Discussion of potential application of a patented NASA process to produce images on x-ray films (UW-22). (Fetzner)

Johnson Space Flight Center, Houston, TX (December 13, 1976).
Met with TU Officer to discuss project UW-35, remote dentistry. (Kudva)

Ames Research Center, Moffett Field, CA (March 18, 1977).
Tour of life science laboratories and discussions with NASA employees of issues related to current BAT problem statements. (Fetzner & Kudva)

Marshall Space Flight Center, MSFC, AL (March 31, 1977).
Discussed methods of implementing closer interactions with TU Officer. Specifically discussed stereoscopic display system and evoked response auditory testing. (Engstrom)

Goddard Space Flight Center, Greenbelt, MD (May 18-20, 1977).
Meeting regarding UW-BAT project on dental equipment. (Kudva)

Lewis Research Center, Cleveland, OH (August 25, 1977).
Meeting regarding nickel-based x-ray film project. Resulted from interest expressed by Picker Corp. in this technology. Two Picker representatives attended, along with TU personnel and scientists from LeRC. (Fetzner)

Jet Propulsion Laboratory, Pasadena, CA (September 21-22, 1977).
Discussed state of the multispectral analysis project and implications for commercialization. Reviewed applications to burn diagnosis and to analysis of tissue viability. (O'Neal)

Goddard Space Flight Center, Greenbelt, MD (October 17-18, 1977).
Attended meeting on LIXI scope to discuss commercialization possibilities. Met with other researchers at center on separate topics. (Kudva)

Jet Propulsion Laboratory, Pasadena, CA (November 10, 1977)
Contacted personnel as part of ongoing interaction between the UW-BAT and field center. (Kudva)

Kennedy Space Flight Center, Florida (November 22, 1977).
Took part in meeting on proposed merger of NASA and other programs in area of computer-aided medical diagnosis. Talked with Dr. Buchanan, KSC Biomedical Office Director, about UW-BAT project involving the NASA IMSS Checklist. (Fetzner & two guests from the University of Wisconsin: Drs. Renner and Currie.)

Ames Research Center, Moffett Field, CA (November 30-December 1, 1977).
Discuss current UW-BAT projects involving personnel from this center and explore possibilities for future interactions between UW-BAT and ARC. (Kudva)

NASA TU Headquarters Office, Washington, DC (March 31-April 1, 1978).
Met with Ray Whitten and others to discuss the contract extension project.

C. TU-SPONSORED MEETINGS

NASA-MSFC Contractors Technology Utilization Workshop, Chicago, IL (February 10, 1977).
Participated with contractor representatives, NASA officials, and IITRI Team in discussions of new technology reporting requirements. (Fetzner & Kudva)

TU Meeting at IITRI, Chicago, IL (March 30-31, 1977).
Discussions of RTOP policy and planning between field center and Team representatives. (Fetzner)

Annual NASA TU Conference, Washington, DC (May 23-26, 1977). (Huston & Fetzner)
Meeting of representatives from all NASA/TU units.

Biomedical RTOP Review, STIF, Baltimore, MD (July 21-22, 1977).
Participated in panel review of FY '78 Biomedical RTOP's with representatives from several NASA/TU units. (Fetzner)

Planning Session for NASA/TU Hearing Aid Project, Washington, D.C. (July 26, 1977).
Met with representatives from DHEW and NASA/TU to discuss solicitation of proposals from NASA field centers to develop an advanced hearing aid. (Fetzner)

Meeting with TU Headquarters Personnel, Washington, D.C. (November 2, 1977).
Discuss UW-BAT programs, particularly work on problems of the aged. (Engstrom)

Review of UW-BAT Program, Washington, D.C. (December 7-9, 1977).
Presentation of work accomplished by the Team as part of a general review of all BAT's by TU Headquarters personnel. (Fetzner)

Gallaudet College, Washington, DC (October 17, 1978).
Attended workshop conference, as requested by TU Headquarters, to participate in discussions of a new RTOP and learn about possible applications of a device for the elderly and handicapped. (Houge)

D. SITE VISITS TO MANUFACTURERS

Meeting with Honeywell Corp. and Mayo Clinic, Minneapolis, MN (August 2-3, 1977).
Joined a contingent of NASA visitors to Honeywell and Mayo Clinic to learn of efforts there in stereofluoroscopy. Discussed NASA/JSC proposal in this area. (Fetzner)

Bendix Corp., Davenport, IA (September 29, 1977).
Invited by engineering manager for Health Care Products of Bendix Instruments and Life Support Division to discuss their proprietary interests in a wearable oxygen supplementation system (UW-46). (Houge)

Meeting on BAT Project, Milwaukee, WI (November 3, 1977).
Talked with private physician and company representatives (D&N Composites) regarding holding tank design and application. (Kudva)

E. CONFERENCE ATTENDANCE

Emergency Medical Services Communications Seminar, College Park, MD (August 9-10, 1976). (Engstrom)

NERAC Seminar, Storrs, CT (September 21-22, 1976).
Meeting arranged by NASA/IAC. (Huston)

Annual Conference of the American College of Surgeons, Chicago, IL (October 10-12, 1976).
Major medical conference (over 17,000 attending); opportunity to gain perspectives and make contacts. (Kudva)

Annual Conference on Engineering in Medicine and Biology, Boston, MA (November 6-10, 1976).
Major bioengineering conference (over 1,000 attending); four papers presented by members of BATeam; opportunity to gain perspectives and make contacts. (Engstrom, Fetzner, Kudva)

Annual Conference of Society for Advanced Medical Systems, Boston, MA November 10-13, 1976).
Forum for consideration of broader design factors, such as social context, organization of resources, etc., regarding health care applications of technology. (Fetzner)

Technical Advisory Seminar (sponsored by the Governor's Committee for People with Disabilities), Madison, WI (November 19, 1976).
Invited to help prepare state plan regarding technical help for the handicapped. (Fetzner & Houge)

American Institute of Chemical Engineers Regional Meeting, Minneapolis, MN (February 24, 1977).
Gave talk entitled "The NASA Earth Mission," as an invited speaker. (Fetzner)

12th Annual Meeting of the Association for the Advancement of Medical Instrumentation, San Francisco, CA (March 13-17, 1977).
Attended to obtain information on state-of-the-art in a diversity of biomedical engineering areas and to make contacts related to BATeam work. (Fetzner & Kudva)

National EMS Communications/Transportation Symposium, Atlanta, GA (March 29-30, 1977)
Reported on NASA communications channel quality monitor, NASA hospital emergency console and possible EMS satellite applications. (Engstrom)

VA/NASA Conference on Habitability in the Extended Care Environment, Minneapolis, MN (September 21-23, 1977).
Attended as part of contingent from NASA to explore possibilities of continued interaction in this area and for technology transfer to problems of the aged. Report from Team sent to KT. (Engstrom, Fetzner, Houge)

Trauma Symposium, Madison, WI (September 30-October 1, 1977). (Engstrom)

105th Annual Meeting of the American Public Health Association, Washington, DC (October 31-November 3, 1977).
Made contacts and learned about current issues and problems in field of public health. (Engstrom)

NIH Instrumentation Symposium, Washington, DC (November 2, 1977).
Learned about state-of-the-art in biomedical instrumentation field from NIH contractors. (Engstrom)

30th Annual Conference on Engineering in Medicine and Biology, Los Angeles, CA (November 5-11, 1977).
Major annual meeting in the field of biomedical engineering. Gathered information on state-of-the-art, made contacts, follow-up on previous interactions. (Fetzner & Kudva)

Annual Meeting of the American Nuclear Society, San Francisco, CA (November 28-29, 1977).
Represented efforts of UW-BAT to help commercialize the GSFC LIXI scope, which was presented at the conference. (Kudva)

Workshop Co-Sponsored by NASA and NIA, Baltimore, MD (December 8, 1977).
Discussions of problems of the aged with the goal of exploring opportunities for NASA to transfer its technologies to this field. (Fetzner)

13th Annual Meeting of the Association for the Advancement of Medical Instrumentation (March 29-31, 1978).
Major national conference in medical device field. Gathered information and contacted people to prepare new problem statements. (Engstrom)

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SPECIAL REPORTS

Along with regular reports called out in the contract, Team members prepared a number of special reports during the contracting period. A list of these special reports follows, with each entry accompanied by the purpose of the report, identification of the intended recipients, and the date that the report was submitted.

* Distribution of Team Resources
Prepared for Len Ault as part of agency-wide survey related to cost containment planning (June 7, 1977).

* Team Status Summary
Prepared for Ray Whitten, Headquarters, Manager of the Biomedical Applications Program, to provide information to be used in a report on all BAT's (August 23, 1977).

* Jointly sponsored NASA/VA conference ("Habitability in Extended Care Environments")
  Report by attendees from the UW-BAT, prepared for Ray Whitten of TU Headquarters (October 25, 1977).

* RTOP Assistance
  Aid given by members of the UW-BAT to Headquarters and field center personnel as part of the preparation of FY '78 TU biomedical RTOP's. Documents of various types (detailed letters, proposals, and reviews) were written for six planned projects (April-August, 1977).

* Reconfigurable Information-Communications-Display System
  Report delivered to NASA/TU Headquarters completing one of the tasks (#4) identified in the contract extension work statement.

SECTION V

CONTRACT EXTENSION PROJECT

CONTRACT EXTENSION PROJECT

Conception of the Plan

Along with other operating units of the NASA Biomedical Applications Program, the UW-BAT began in late 1977 to concentrate attention on possibilities for the transfer of NASA technologies to help elderly people in this country. As one part of this effort, the UW-BAT proposed to study, in more depth than usually given to problems, the specific needs of the aged and to search for applicable NASA technologies.

Plans for such an in-depth study were formulated near the end of the period originally designated for the BAT contract (July 1976 through December 1977). These were submitted to the contract monitor at GSFC as a request for a no-cost contract extension to complete the cited study. After concurrence with TU Headquarters, the request was granted. The original extension was for six months, but a subsequent request from the Team for extension through calendar year 1978 was also granted. This project, therefore, was conducted during calendar year 1978 as the sole activity under the contract in force during 1977. Regular BAT operations during calendar year 1978 were conducted under a separate contract, reports for which are provided as separate documents.

The present discussion is a summary of work done on the special project. A full presentation of this work can be found in the report entitled "Definition of Problems of Persons in Sheltered Care Environments," submitted simultaneously, but under separate cover by the UW-BAT.

Statement of Work

Task 1: Gather information on the subject from medical doctors, nursing home administrators, researchers, government workers, special projects operated to meet needs of the elderly, industry sources, and published documents. Organize this information to define and characterize needs of the elderly, paying special attention to those needs that seem to offer opportunities for the new application of technologies. The contractor shall prepare a list of these needs, arranged in some useful order of importance in terms of the overall goals of the project.

Task 2: The contractor shall search for NASA technologies applicable to the needs of the elderly living in sheltered environments. These candidate technologies shall be identified in documented form. Matching of identified technologies with defined needs shall be attempted for those needs ranking highest in importance.

Task 3: An effort will be made to attack at least one matched need/NASA solution in depth. A strategy for implementing the solution will be developed. This will be forwarded to the technical monitor for consideration, either as an RTOP draft or alternate plan of action.

Task 4: The contractor shall make other recommendations as appropriate in order to make best use of the information derived under this extension.

Task 5: A planning workshop shall be conducted. The subject of the workshop shall be to examine, in depth, the application of NASA technologies to one or more needs of the elderly living in sheltered

environments. Results of this planning effort will serve as the basis for the involvement of field center staff in the application of NASA technology to these needs through an RTOP arrangement.

Task 6: A small-scale demonstration of an actual application of aerospace technology to one of the identified needs will be conducted. A report giving details of the application and results from the demonstration and potential for commercialization will be produced.

Task 7: A final report will be prepared summarizing the work done on each of the tasks, as well as directions established, activities completed, and RTOP's written as a consequence of this extension project.

Accomplishments

A thorough study of the problem was undertaken by the UW-BAT through meetings with gerontologists, nursing home operators, private foundations, industry representatives and groups for the elderly. Out of these discussions, a long list of needs was prepared. The list was carefully considered by others not involved with the list preparation to rank the relative importance of the needs in several categories. These categories included the scope of expected benefits, technical feasibility, and applicability of NASA technologies. From the ranked results, a selection was made of those most likely to benefit from increased NASA attention (Task 1).

Next, a wide search of applicable NASA technologies was conducted, concentrating on those most appropriate to the highest ranked candidates above (Task 2). The best fit resulted in the selection of one problem--

the lack of a systems approach to the provision of aids and controls to the elderly--for study in greater depth (Task 3).

Specifications for the proposed solution to the problem involving extensive applications of NASA technologies were developed. Recommendations for concerted NASA action based upon the chosen problem and solution specifications were addressed to NASA field center and headquarters officials (Task 4).

While awaiting a NASA response to the above recommendations, the Team organized and held a planning workshop to bring the views of more people into the project (Task 5). Out of this meeting, another set of recommendations was produced to guide efforts to carry forward work on the chosen problem over a wide spectrum of possibilities.

Besides concept planning, the Team applied some of the ideas being considered to a small-scale demonstration of a prototype system. This was developed in cooperation with local health and industry officials. It was shown, in operation, to the contract technical monitor, Mr. Donald Friedman, and the TU Biomedical Applications Program Manager, Mr. Raymond Whitten, during a site visit of the UW-BAT in November 1978 (Task 6).

It was intended, when the project was conceived, that the Team would screen the enormous number of special needs of the elderly in an attempt to uncover those anenable to solution under the NASA TU program. We have completed such an analysis, made specific recommendations, and demonstrated a prototype embodiment of an idea that we believe merits further action by TU. Now the task is to bring the concept to full-scale development, a goal that will be pursued by the UW-BAT under its normal contract responsibilities.

APPENDICES

APPENDIX A

PROBLEM STATEMENTS CONSIDERED DURING REPORTING PERIOD[1]

Number	Title	Status[2]
UW-6	Unobtrusive Biofeedback Device for Treatment of Petit Mal Epilepsy	A4
UW-7	An Unobtrusive Device for Suppression of Acoustiomotor Epilepsy	I8
UW-10	Coating of Chronically Implanted Electronic Assemblies	A5
UW-11	Family Practice Clinic Design	I4
UW-15	Wide Area Medical Communications	A6
UW-16	Human Engineering Factors in Hospital Communication Hardware Design	I8
UW-19	Early Stroke Detection	I3/I6
UW-20	Abnormal Brain Wave Detection	I3/I6
UW-22	Non-Silver-Bearing Film for X-Ray Use	I4/I7
UW-23	Conformable and Autoclavable Return Electrode for Electrosurgery	A5
UW-24	Automated Patient Tracking System	A2
UW-25	Ruggedized Cable Assembly for Patient Control of Nurse Alerting and Environmental Control System	I4
UW-26	An EEG Switch	I3/I6

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[1] Previously inactivated problems have been deleted from list.

[2] Status at the end of the reporting period. For an explanation of status codes, see the following coding keys on active (A-type) and inactivated (I-type) problems.

Number	Title	Status
UW-27	Unobtrusive Alertness Monitor	I8
UW-28	A Telemetry Device to Monitor Loading and Stress Patterns in Metallic Implants	I4
UW-29	Highly Regulated Differential Temperature Control System	I4
UW-30	Multi-Spectral Analysis of Tissue Viability	A3
UW-31	Improved Pump Reliability for Extended Circulatory Bypass	I9
UW-32	New Femoral Head Prosthesis Design to Improve Long-Term Stability	A4
UW-33	Miniaturized Force Transducer for Gastrointestinal Motility Studies	A2
UW-34	System to Provide Quantifiable Vestibular Stimulation and Motor Response in Children with Delayed Development	A2
UW-35	Portable Dental Equipment	A5
UW-36	Reliable, Inexpensive Relative Humidity Transducer	I9
UW-37	Primary Care Education and Response	A5
UW-38	Home Water Filtration Device	I6
UW-39	Pupillometer--A Device to Continuously Measure Pupil Diameter	A4
UW-40	Absorptiometric Techniques	I3/I6
UW-41	Design Improvements for Neonatal Intensive Care Incubators	A3
UW-42	Diagnostic Radiographic Image Storage System	A2
UW-43	Intracranial Pressure Display/Alarm System	A2
UW-44	Microwave Blood Warmer for Extracorporeal Circulation	I4
UW-45	Sorbents for Detoxification of Uremic Patients	A3
UW-46	Self-Contained Oxygen Supply for Use by Patients with Chronic Obstructed Pulmonary Disease	A3
UW-47	Hand and Foot Warmers for Patients with Raynaud's Syndrome	A7
UW-48	Treadmill for Home Use by Patients with Chronic Obstructive Pulmonary Disease	A5
UW-49	Sleep Monitoring Systems	A3
UW-50	Improved Device for Treatment of Esophageal Achalasia	A2

APPENDIX B

CODING KEY: ACTIVE PROBLEMS

A1 - *Definition.* A problem statement has been prepared following consultation with the client, study of the unique character of the problem, and preliminary analysis of possible methods of solution.

A2 - *Search.* A systematic hunt through the NASA organization and records is being conducted to determine if a ready solution to the problem exists.

A3 - *Evaluation.* A ready solution to the problem has apparently been found and is being tried out.

A4 - *Holding.* A ready solution to the problem has apparently been found, but is not being implemented.

A5 - *Engineering.* A near-ready solution to the problem has apparently been found and modifications and/or prototype development is being planned or conducted.

A6 - *Dissemination.* The problem has been solved with the direct help of NASA; a documentation package is being prepared for distribution.

A7 - *Commercialization.* The problem has been solved with the direct help of NASA; attempts are now underway to encourage private enterprise to turn the solution into a commercial product.

A8 - *Other.* The problem has a unique status not covered by the classifications above.

APPENDIX C

CODING KEY: INACTIVATED PROBLEMS

I1 - The client does not have adequate resources or interest at present to justify BATeam work on the problem.

I2 - The client has solved the problem on his own.

I3 - Searching efforts by the BATeam have not turned up any promising NASA solutions to the problem.

I4 - Searching efforts by the BATeam have revealed a promising NASA solution, but no implementation by the client appears likely at this time.

I5 - The original problem statement was too broad; it has been rewritten to more clearly define one or more subproblems and each has been separately identified.

I6 - The problem was dropped because it did not fit the present goals, priorities, or resources of the BATeam.

I7 - The problem was transferred out of the jurisdiction of the UW-BATeam.

I8 - Work has been completed on the problem and a NASA transfer has occurred.

I9 - Work has been completed on the problem and an impact--a satisfactory non-NASA solution to the problem--accomplished with the help of the BATeam.

I10- Other.

APPENDIX D
(Roster)

Biomedical Applications Team
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